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SCIENTIFIC DATA REVIEWS
EPA SERIES 361

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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: **PP#2E04141. MYCLOBUTANIL. REVISED** Tolerance on Imported Bananas.

DP Barcode: D236675 Caswell #: 723K
PRAT Case #:283970 Chemical #: 128857
40 CFR 180.443 Class: Fungicide

FROM: Nancy Dodd, William Dykstra, Brenda Tarplee, and Martha Lamont
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THROUGH: Melba Morrow, Branch Senior Scientist
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TO: Connie Welch, PM#21
Registration Division (7509C)

INTRODUCTION

This memo supersedes the tolerance petition response from HED dated 25-NOV-1997 for myclobutanil on imported bananas. Changes include a refined residential risk estimate and subsequent changes to the aggregate risk assessment.

Rohm and Haas has requested the establishment of a permanent tolerance for the combined residues of myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) on bananas. The bananas will be imported.

Permanent tolerances are established (40 CFR 180.443, 40 CFR 185.4350, and 40 CFR 186.4350) for residues of myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-

(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) on almonds, apples, cottonseed, grapes, sweet and sour cherries, and stone fruits (except cherries).

Permanent tolerances are established (40 CFR 180.443) for combined residues of myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free) on animal commodities except milk. A permanent tolerance is established for myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolites alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) and alpha-(4-chlorophenyl)-alpha-(3,4-dihydroxybutyl)-1H-1,2,4-triazole-1-propanenitrile in milk.

Myclobutanil is currently registered for outdoor residential and greenhouse use on annuals and perennials, turf, shrubs, trees, and flowers.

I. EXECUTIVE SUMMARY

HED recommends for the proposed tolerance of 4.0 ppm for the combined residues of myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) on bananas.

For risk assessment purposes only, HED concludes that residues resulting from the proposed use will not exceed 0.8 ppm in banana pulp.

Aggregate risks from myclobutanil do not exceed HED's level of concern for infants, children, or adults.

II. SCIENCE ASSESSMENT

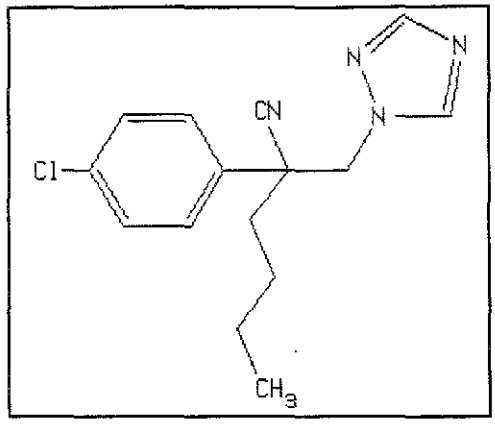
A. PHYSICAL AND CHEMICAL PROPERTIES ASSESSMENT

Product Chemistry data required for registration have been submitted and are satisfactory. The technical has previously been registered.

1. Description of Chemical

Myclobutanil is a fungicide for control of powdery mildew and rust.

Figure A. Myclobutanil



Empirical Formula: $C_{15}H_{17}ClN_4$
Molecular Weight: 288.78
CAS Registry No.: 88671-89-0
Shaughnessy/Chemical No.: 128857
Caswell No.: 723K
CAS name: alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile

2. Identification of Active Ingredient

Table 1: Manufacturing and Impurity Data for Myclobutanil Technical (RH-3866 Technical Fungicide, EPA Registration Number 707-210)

OPPTS GLN	MRID or Accession #	Status[1]	Deficiency
830.1550: Product Identity and Composition	072895 406054-01	A	
830.1600: Description of Materials Used to Produce the Product	072895	A	
830.1620: Description of Production Process	072895	A	
830.1650: Description of Formulation Process	072895	A	
830.1670: Discussion of Formation of Impurities	072895 406054-01	A	
830.1700: Preliminary Analysis	072895 406054-01	A	
830.1750: Certified Limits	406054-01	A	
830.1800: Enforcement Analytical Method	072895 073596 406054-01	A	
830.1900: Submittal of Samples	See "2" below	A	

[1] A = Acceptable. N = Unacceptable

[2] Analytical reference standards for myclobutanil and its metabolites were submitted to the Pesticides and Industrial Chemicals Repository, RTP, NC.

Table 2. Physical and Chemical Properties for Myclobutanil Technical, EPA Registration Number 707-210			
OPPTS GLN	Accession/ MRID #	Status[1]	Result
830.6302: Color	072895 141683 266121 256773 406054-02	A	light yellow
830.6303: Physical State	072895 141683 266121 256773 406054-02	A	solid
830.6304: Odor	072895 141683 266121 256773 406054-02	A	odor of organosulfur compounds, moderately intense

Table 2. Physical and Chemical Properties for Myclobutanil Technical, EPA Registration Number 707-210			
OPPTS GLN	Accession/ MRID #	Status[1]	Result
830.6313: Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	072895 141683 266121 256773 406054-02	A	thermal: No loss of active ingredient after 2.5 years at 25°C. Accelerated thermal stability studies (ARC) showed no evidence of major instability below 300°C. sensitivity to metal ions and metal: Inert to stainless steel as purification of the technical is conducted at >250°C on SS 316/304 surfaces. Stable to metal ions as the technical is prepared in the presence of sodium and potassium ions at 150°C for prolonged periods. sensitivity to sunlight[3]: Halflife for photodegradation in soil is 144 days.

Table 2. Physical and Chemical Properties for Myclobutanil Technical, EPA Registration Number 707-210			
OPPTS GLN	Accession/ MRID #	Status[1]	Result
830.6314: Oxidation/Reduction; Chemical Incompatibility	N/A[2]		
830.6315: Flammability	N/A[2]		
830.6316: Explodability	N/A[2]		
830.6317: Storage Stability	N/A[2]		
830.6319: Miscibility	N/A[2]		
830.6320: Corrosion Characteristics	N/A[2]		
830.6321: Dielectric Breakdown Voltage	N/A[2]		
830.7000: pH	N/A 406054-02		The technical material cannot be diluted or dispersed in water. The pH of a saturated aqueous solution of this material is about 6-7, the same as the background value of the water used.
830.7050: UV/Visible Absorption	New requirement		This new requirement will be required in the future under reregistration.
830.7100: Viscosity	N/A[2]		

Table 2. Physical and Chemical Properties for Myclobutanil Technical, EPA Registration Number 707-210			
OPPTS GLN	Accession/ MRID #	Status[1]	Result
830.7200: Melting Point/Melting Range	072895 141683 266121 256773 406054-02	A	63-68°C
830.7220: Boiling Point/Boiling Range	N/A		
830.7300: Density/Relative Density/Bulk Density	072895 141683 266121 256773 406054-02	A	density: 1.22 g/cc at 23°C
830.7370: Dissociation Constants in Water	N/A 406054-02		The pure ingredient does not have acidic hydrogens and is expected to be a very weak base. Attempts to measure pKa by titration with acid (HCl) and base (NaOH) failed to detect any inflection on the titration curve, indicating little or no dissociation.
830.7520: Particle Size, Fiber Length, and Diameter Distribution	New requirement		This new requirement will be required in the future under reregistration.

Table 2. Physical and Chemical Properties for Myclobutanil Technical, EPA Registration Number 707-210			
OPPTS GLN	Accession/ MRID #	Status	Result
830.7550: Partition Coefficient (n-octanol/water), Shake Flask Method or 830.7560: Partition Coefficient (n-octanol/water), Generator Column Method or 830.7570: Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	141683 406054-02	A	871/1 at 25°C for pure active ingredient
830.7840: Water Solubility: Column Elution Method; Shake Flask Method or 830.7860: Water Solubility, Generator Column Method	072895 141683 266121 256773 406054-02	A	For pure active ingredient in: water 142 ppm at 25°C hexanes << 1g/100g >50 g/100 g: xylene amyl acetate cyclohexanone DMF methyl ethyl ketone Measured by analytical method for RH-3866 (a capillary GLC method)

Table 2. Physical and Chemical Properties for Myclobutanil Technical, EPA Registration Number 707-210			
OPPTS GLN	Accession/ MRID #	Status[1]	Result
830.7950: Vapor Pressure	072895 141683 266121 256773 406054-02	A	1.6×10^{-6} torr/25°C for pure active ingredient

[1] A = Acceptable; N = Unacceptable (See Deficiency); N/A = Not Applicable

[2] Not required for technical

[3] Sensitivity to sunlight is no longer required.

B. HUMAN RISK ASSESSMENT

1. Hazard Assessment

The toxicological data base on myclobutanil is adequate and will support registration (Toxicology Profile, 7/12/94).

a. Acute Toxicity

The following table summarizes acute toxicity values and categories for myclobutanil:

Table 3. Acute Toxicity of Myclobutanil Technical

GDLN	STUDY	RESULTS
81-1	Acute Oral Toxicity in Rats Accession #072896 Report #84-063A Date: 7/19/84 Acceptable	LD_{50}: 1.6 g/kg (males) LD_{50}: 2.29 g/kg (females) TOXICITY CATEGORY: II12I
81-2	Acute Dermal Toxicity in Rabbits Accession #072896 Report #84R-134A Date: 7/30/84 Acceptable	LD_{50}: >5000 mg/kg TOXICITY CATEGORY: III
81-3	Acute Inhalation Toxicity in Rats MRID #403571-01 Report #87R-028 Date: 8/31/87 Acceptable	LC_{50}: >5.1 mg/L (four hour exposure) TOXICITY CATEGORY: IV
81-4	Primary Eye Irritation in Rabbits Accession #072896 Report #84R-134A Acceptable	Primary Irritation Score: Not given in DER TOXICITY CATEGORY: I Severe eye irritant
81-5	Primary Dermal Irritation in Rabbits Accession #072896 Report #84R-134A Date: 8/3/84 Acceptable	Primary Irritation Score: Not given in DER TOXICITY CATEGORY: IV Non-irritating to the skin under conditions of test.

Table 3. Acute Toxicity of Myclobutanil Technical		
GDLN	STUDY	RESULTS
81-6	Dermal Sensitization in Guinea Pigs MRID #403571-02 Report #87R-035 Date: 6/25/87 Acceptable	Buehler method. 12 pigs, 10 induction doses of 0.4 ml of 50% w/w formulation in 80% ethanol. 50% w/w formulation in acetone used at challenge + rechallenge. Minimal erythema at 24 & 48 hrs. Positive sensitizing reaction.

b. Subchronic Toxicity

The following table summarizes subchronic toxicity values and categories for myclobutanil:

Table 4. Subchronic Toxicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
82-1(a)	Subchronic Feeding in Rats (13 weeks) Accession #'s 072897 and 072898 Report #83R-068 Date: 8/7/84 Core Grade: Minimum	NOEL: 1000 ppm LOEL: 3000 ppm Effects: increased liver and kidney weights; hypertrophy, necrosis in liver; pigmentation in convoluted kidney tubules; vacuolated adrenal cortex.

Table 4. Subchronic Toxicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
82-1(b)	Subchronic Feeding in Dogs (13 weeks) Accession #072899-072900 Report #83R-204 Date: 8/7/84 Core Grade: Minimum	NOEL: 10 ppm LOEL: 200 ppm Effects: Technical myclobutanil (81.1%) tested at: 0, 10, 200, 800 or 1600 ppm (0, 0.34, 7.26, 29.13 or 56.80 mg/kg/day (males) and 0, 0.42, 7.88, 32.43 or 57.97 mg/kg/day (females). At 200 ppm and above, hepatocellular centrilobular or midzonal hypertrophy was observed in males. At 800 ppm and above, the same effect was observed in females. In addition, increases in alkaline phosphatase, in absolute liver weights in both sexes and in relative liver weights in males were observed. At 1600 ppm, all the previous effects plus increases in relative liver weights in females, a suggestion of mild red cell destruction or mild anemia, and decreases in body weight and food consumption (possibly related to palatability) were observed.

Table 5. Subchronic Toxicity of Myclobutanil, **40% Formulation**		
GDLN	STUDY	RESULTS
82-2	28-day dermal in rats Accession #266080 Report #85R-240 Date: 8/29/86 Minimum	NOEL for systemic effects: >100 mg ai/kg/day. NOEL for skin irritation: 10 mg a.i./kg/day LEL: 100 mg a.i./kg/day for both formulations. <u>Effects</u>: Study conducted on two formulations: 41.36% (40WP) and 24.99% (2EC) formulation. 2EC formulation applied at either 1, 10 or 100 mg a.i./kg and 40WP formulation applied at 100 mg a.i./kg. Rats treated 1x/day for a total of 19-20 treatments over a 4-week period. No systemic effects observed at any dose level for either formulation. Microscopic changes, indicating irritation were observed in the skin. These included epidermal necrosis, epidermal thickening, and/or subacute/chronic inflammation of the dermis and were observed in all groups, including controls; however, the changes were of lesser severity and at a lower incidence in the vehicle control and in the mid- and low dose groups of the 2EC formulation. The 40WP group exhibited a minimal to mild degree of chronic inflammation and epidermal thickening with 2 animals exhibiting eschar formation. This study is acceptable for regulatory requirement for a 21-day dermal study for both the technical and the formulation (see Data Gaps Comments).

c. Chronic Toxicity

The following table summarizes chronic toxicity values and categories for myclobutanil:

Table 6. Chronic Toxicity of Myclobutanil (Technical)

GDLN	STUDY	RESULTS
83-1	Chronic feeding study in dogs Accession #165248 Report #84R-078 Date: 10/15/86 Core Grade: Minimum	NOEL: 100 ppm LOEL: 400 ppm Effects: 91.4% material fed in the diet to 6 dogs/group/dose at levels of 0, 10, 100, 400 or 1600 ppm for one year. LEL: 14.28 mg/kg/day; the NOEL: 3.09 mg/kg/day based on hepatocellular hypertrophy, increases in liver weights, "ballooned" hepatocytes and increases in alkaline phosphatase, SGPT and GGT. In addition, there were some possible slight hematological effects. Full histopathology examinations not submitted for mid- and low dose level groups.

d. Carcinogenicity

The following tables summarize carcinogenicity values and categories for myclobutanil:

Table 7. Carcinogenicity of Myclobutanil (Technical)

GDLN	STUDY	RESULTS
83-2(a)	Oncogenicity study in mice Accession #164990 Report #84R-023 Date: 10/17/86 Core Grade: Minimum when considered with MRID #428091-02	NOEL: 100 ppm (Systemic) LOEL: 500 ppm (Systemic) Effects: 90.4% test material given to male and female Crl:CD®-1(ICR)BR mice in diet for 24 months at 0, 20, 100 or 500 ppm (0, 2.7, 13.7 or 70.2 mg/kg/day for males; 0, 3.2, 16.5, or 85.2 mg/kg/day for females). LEL based on increased MFO (male and female); increased SGPT (male) and increased absolute and relative liver weights (male and female); increased incidences and severity of centrilobular hepatocytic hypertrophy, Kupffer cell pigmentation, periportal punctate vacuolation and individual hepatocellular necrosis (male); and increased incidences of focal hepatocellular alterations and multifocal hepatocellular vacuolation (male and female). Not tested at high enough dose levels in females. MRID No. 428091-02 tested at sufficiently high dose levels [2000 ppm (393.5 mg/kg/day)], no oncogenic effects observed. The two studies together satisfy the regulatory requirement for an oncogenicity study in the mouse.

Table 8. Carcinogenicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
83-2(a)	Oncogenicity study in mice MRID #428091-02 Report # 89R-261 Date: 3/17/93 Core Grade: Minimum when considered with Accession #164990	NOEL: Not established LOEL: 2000 ppm (393.5 mg/kg/day) Effects: Technical (92.9%) administered to female Crl:CD®-1 (ICR)BR mice at 0 or 2000 ppm (393.5 mg/kg/day) in diet. Decreases in body weight & body weight gain; increases in liver weights; hepatocellular hypertrophy; hepatocellular vacuolation; necrosis of single hypertrophied hepatocytes; yellow-brown pigment in the Kupffer cells and cytoplasmic eosinophilia and hypertrophy of the cells of the zona fasciculata area of the adrenal cortex. Not oncogenic under the conditions of the study. Study is only 18 months; however, the two studies together satisfy the regulatory requirement for an oncogenicity study in the mouse.

Table 9. Carcinogenicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
83-2(b)	Oncogenicity study in rats MRID #428091-01 Report #HWA 417-471, RH-89RC-260 Date: 2/12/93 Core Grade: Guideline when taken in conjunction with Accession #165247	NOEL: Not established LOEL: 2500 ppm (only dose tested) Effects: (92.9%) administered to male and female Sprague-Dawley Crl:CD®BR VAF/Plus® rats at 0 or 2500 ppm (125 mg/kg/day) in the diet. Testicular atrophy and decreases in testes weights; increases in the incidences of centrilobular to midzonal hepatocellular enlargement and vacuolization in the liver of both sexes; increases in bilateral aspermatogenesis in the testes; increases in the incidence of hypospermia and cellular debris in the epididymides; and increased incidence of arteritis/periarteritis in the testes. No oncogenic effects observed. Satisfies regulatory requirement when taken with Accession #165247.

Table 10. Carcinogenicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
83-5	Chronic Feeding/ Oncogenicity study in rats Accession #165247 Report #85RC-61 Date: 10/24/86 Core Grade: Guideline when taken in conjunction with MRID #428091-01	NOEL: 2.49 mg/kg/day LOEL: 9.84 mg/kg/day Effects: Technical (90.4% and 91.4% pure) administered to male and female Sprague-Dawley rats in diet for 24 months at 25/35/50, 100/140/200 & 400/560/800 ppm [2 weeks/2 weeks/to termination; 0, 2.49, 9.84 or 39.21 mg/kg/day (males); 0, 3.23, 12.86 or 52.34 mg/kg/day (females)]. Decrease in testes weights and increase in testicular atrophy. Not tested at high enough dose levels. MRID #428091-01 tested at sufficiently high dose levels (2500 ppm: 125 mg/kg/day), no oncogenic effects observed. Satisfies regulatory requirement when taken with MRID #428091-01.

e. Developmental Toxicity

The following table summarizes developmental toxicity values and categories for myclobutanil:

Table 11. Developmental Toxicity of Myclobutanil (Technical)

GDLN	STUDY	RESULTS
83-3	Teratology Study in Rabbits Accession #164971 Report #83R-217 Date: 11/15/84 Core Grade Minimum	Maternal NOEL: 60 mg/kg/day Maternal LOEL: 200 mg/kg/day Effects: technical 90.4% administered to male New Zealand White rabbits 0 (water control), 0 (Hi-Sil control), 20.0, 60.0 or 200.0 mg/kg/day a.i. by oral gavage (5 ml/kg b.w.) on days 7-19 of gestation. Reduced body weight and body weight gain during the dosing period, clinical signs of toxicity and possibly abortions. Developmental NOEL: 60 mg/kg/day Developmental LOEL: 200 mg/kg/day Effects: Increases in number of resorptions, decreases in litter size and a decrease in the viability index.

Table 11. Developmental Toxicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
83-3	Teratology Study in Rats Accession #141672 Report # 83R-024 Date: 6/22/84 Core Grade Minimum	Maternal NOEL: 93.8 mg/kg/day Maternal LOEL: 312.6 mg/kg/day Effects: Technical (84.5%) administered to Sprague-Dawley [Crl:CD-(SD)BR] rats at 0, 31.26, 93.77, 312.58 or 468.87 mg/kg/day by oral gavage from gestation days 6-15, inclusive. Rough hair coat and salivation at 312.6 and salivation, alopecia, desquamation and red exudate around mouth at 468.87 mg/kg/day. Developmental NOEL: 93.8 mg/kg/day Developmental LOEL: 312.6 mg/kg/day Effects: Increased incidences of 14th rudimentary and 7th cervical ribs at 312.6 and 468.9 mg/kg/day.

f. Reproductive Toxicity

The following table summarizes reproductive toxicity values and categories for myclobutanil:

Table 12. Reproductive Toxicity of Myclobutanil (Technical)

GDLN	STUDY	RESULTS
83-4	Multigeneration Reproduction Toxicity in Rats Accession #'s 143766 and 149581 Report #84R-117 Date: 8/21/85 Core Grade Guideline	Systemic NOEL: 50 ppm (2.5 mg/kg/day) Systemic LOEL: 200 ppm (10 mg/kg/day) Effects: Technical (84.5% pure administered to male and female CRL:CD(SD)BR rats at 0, 50, 200 or 1000 ppm in diet (0, 2.5, 10 or 50 mg/kg/day). Increased liver weights and hepatocellular hypertrophy. Reproductive NOEL: 200 ppm (10 mg/kg/day) Reproductive LOEL: 1000 ppm (50 mg/kg/day) Effects: Increased incidence in the number of stillborns and atrophy of the testes, epididymides and prostate. Developmental NOEL: 200 ppm (10 mg/kg/day) Developmental LOEL: 1000 ppm (50 mg/kg/day) Effects: Decrease in pup body weight gain during lactation.

g. Mutagenicity

The following tables summarize mutagenicity values and categories for myclobutanil:

Table 13. Mutagenicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
84-2(a)	Gene Mutation Assay (Ames Test) Accession #072901 Report #83R-0246 Date: 1/31/84 Acceptable	No appreciable increase in the reversion to histidine protrophy of 4 S. typhimurium strains at 75 to 7500 ug/plate with & without S-9 activation.
84-2(a)	Gene Mutation Assay Mammalian Cells Accession #072901 Report #84R-046 Date: 5/29/84 Acceptable	Negative with and without metabolic activation up to 175 ug/ml.

Table 14. Mutagenicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
84-2(b)	Structural Chromosomal Aberration Assay In vivo cytogenetics Accession #072901 Report #84R-0074 Date: 7/23/84 Acceptable	The level of 650 mg/kg did not cause a significant increase in chromosomal aberrations in bone marrow cells sampled over the entire mitotic cycle.

Table 14. Mutagenicity of Myclobutanil (Technical)		
GDLN	STUDY	RESULTS
84-2(b)	Structural Chromosomal Aberration Assay In vitro cytogenetics Accession #266099 Report #20990 Date: 4/85 Acceptable	Did not induce chromosomal aberrations with & without metabolic activation under the conditions of the study up to 200 ug/ml.
84-2(b)	Structural Chromosomal Aberration Assay Dominant Lethal Test Accession #266101 Report #86RC-0054 Date: 10/10/86 Acceptable	Did not induce dominant lethal mutations under conditions of study at dose levels up to 735 mg/kg.
84-2(c)	Other Genotoxicity Assays (Unscheduled DNA Synthesis) Accession #266100 Report #86R-084 Date: 7/22/86 Acceptable	Did not induce an increase in unscheduled DNA synthesis up to toxic dose. 0.1-1000 ug/ml tested.

h. Metabolism

The following table summarizes metabolism values and categories for myclobutanil:

Table 15. Metabolism of Myclobutanil (Technical)

GDLN	STUDY	RESULTS
85-1	Metabolism in Mice Accession #266102 Report #83R-175 Date: 8/29/86 Acceptable	Rapidly absorbed and excreted. Completely eliminated by 96 hrs. Extensively metabolized prior to excretion. Metabolic patterns similar for both sexes. Disposition & metabolism after pulse administration is linear over dose range.
85-1	Metabolism in Rats Accession #266103 Report #83R-144 Date: 8/28/86 Acceptable	Completely and rapidly absorbed. Extensively metabolized and rapidly and essentially completely excreted. Elimination of label from plasma biphasic and evenly distributed between urine and feces. No tissue accumulation after 96 hours.
85-1	Metabolism in Rats Accession #072904 Report #310-84-16 Date: 6/22/84 Acceptable	At least 7 major metabolites recovered and identified. Highest amounts of radioactivity found in liver, kidneys, large and small intestines. No tissue accumulation.

i. Neurotoxicity

There have been no clinical neurotoxic signs or other types of neurotoxicity observed in any of the evaluated toxicology studies. The Hazard ID Assessment Review Committee did not recommend that a developmental neurotoxicity study be required for myclobutanil. The following information was considered in the weight-of-evidence evaluation:

- Myclobutanil does not appear to be a neurotoxic chemical.
- The toxicology profile for this chemical did not indicate that there were any treatment-related effects on the central

or peripheral nervous system. No acute or subchronic neurotoxicity studies in rats or delayed neuropathy studies in chickens were available for review so there was no evaluation of the nervous system following perfusion.

- No evidence of developmental anomalies of the fetal nervous system were observed in the prenatal developmental toxicity studies in either rats or rabbits at maternally toxic oral doses up to 468.9 and 200 mg/kg/day, respectively.

j. Other Toxicological Considerations

Myclobutanil has a complete data base and no other toxicological concerns have been identified in the evaluated studies.

2. Dose/Response Assessment

a. Reference Dose (RfD) for Myclobutanil

The RfD is currently established to be 0.025 mg/kg/day based on the NOEL from the chronic feeding study in the rat (2.49 mg/kg/day; MRID #00165247) and a safety factor of 100 [10 for intraspecies and 10 for interspecies]. The LOEL for the chronic rat feeding study is 9.84 mg/kg/day based on decreased testicular weight and increased testicular atrophy. The Hazard ID Assessment Review Committee noted that the dose of 2.49 mg/kg/day established in the above study is supported by the Parental Systemic Toxicity NOEL and LOEL established in the Two-Generation reproduction study in rats. In that study the NOEL was 2.5 mg/kg/day and the LOEL was 10 mg/kg/day. The Committee determined that the **10 x** factor to account for enhanced sensitivity of infants and children (as required by FQPA) **should be removed.** A UF of 100 is adequate because of the following:

(i) Developmental toxicity studies showed no increased sensitivity in fetuses as compared to maternal animals following *in utero* exposures in rats and rabbits.

(ii) A two generation reproduction toxicity study in rats showed no increased sensitivity in pups that were compared to adults.

(iii) The toxicology data base is complete and there are no data gaps.

The Joint Meeting on Pesticide Residues (JMPR) established an ADI (RfD) of 0.03 mg/kg/day.

b. Carcinogenic Classification

Myclobutanil is classified as Category E: not carcinogenic in two acceptable animal studies. Q_1^* is not applicable.

c. Other Toxicological Endpoints

i. Acute Dietary (1 day)

No appropriate toxicological endpoint was found for an acute dietary risk assessment.

ii. Dermal absorption

The Committee determined that a dermal absorption factor of 100% should be used for risk assessment because 1) a dermal absorption study was not available with the technical and 2) a dermal absorption factor could not be estimated due to the lack of comparative NOELs/LOELs from oral and dermal toxicity studies in the same species with the technical. The dermal absorption factor is required for Intermediate and Long-Term dermal risk assessment since oral doses were selected for these exposure periods. Dermal absorption is not required for Short-Term dermal exposure risk assessment since a dermal dose from a 28-day dermal toxicity study was selected for this time period.

iii. Short-Term Occupational and Residential Exposure (1-7 days)

No 21-day dermal study is available on the technical material. However, a 28-day dermal study (Accession #266080) is available on two formulations: the 41.36% (40WP) formulation and the 24.99% (2EC) formulation. In this study, the 24.99% formulation was applied at either 1, 10 or 100 mg **a.i.**/kg and the 41.36% formulation was applied at 100 mg **a.i.**/kg in a constant volume of 1.5 mg/kg. Rats were treated once/day for a total of 19-20 treatments over a 4-week period. No systemic effects were observed at any dose level for either formulation. Microscopic changes, indicating irritation, were observed in the skin. These included epidermal necrosis, epidermal thickening, and/or subacute/chronic inflammation of the dermis and were observed in all groups, including controls; however, the changes were of lesser severity and at a lower incidence in the vehicle control and in the mid- and low dose groups of the 2EC formulation. The 40WP group exhibited a minimal to mild degree of chronic inflammation and epidermal thickening with 2 animals exhibiting eschar formation. **The NOEL for systemic effects is greater than 100 mg a.i./kg/day. The NOEL for skin irritation is 10 mg**

a.i./kg/day and the LEL is 100 mg a.i./kg/day for both formulations.

Endpoint and dose for use in risk assessment: Systemic NOEL = **≥100 mg a.i./**kg/day (HDT); a LOEL was not established.

The systemic NOEL is greater than 100 mg active ingredient/kg/day (highest dose tested). 100 mg/kg/day will be the dose level used for risk assessment.

iv. Intermediate Term Occupational and Residential Exposure (1 week to several months)
(MRID #'s 00143766, 00149581)

Technical myclobutanil, 84.5% pure was tested in a 2-generation reproduction study with male and female CRL:CD(SD)BR rats at the following dose levels: 0, 50, 200 or 1000 ppm (**2.5, 10.0 and 50** mg/kg/day) in the diet throughout the study. At 200 ppm, centrilobular hepatocellular hypertrophy was observed in the P_2 males. This was supported by slight but statistically significant increases in liver weights in males. At 1000 ppm, centrilobular hepatocellular hypertrophy was observed in both sexes in the P_1 and P_2 generations. These were again supported by slight but statistically significant increases in liver weights. **Parental (systemic) toxicity NOEL: 50 ppm (2.5 mg/kg/day; LEL: 200 ppm (10 mg/kg/day) based on hepatocellular hypertrophy and increases in liver weights.**

At 1000 ppm, an increase in the number of stillborn or % born dead was observed in both generations. In addition, multifocal or diffuse testicular atrophy was observed in males in the P_2 generation. Increased necrotic spermatocytes/spermatids or decreased spermatozoa and atrophy of the prostate were also observed in these animals. **Reproductive NOEL: 200 ppm (10 mg/kg/day); LEL: 1000 ppm (50 mg/kg/day) based on an increased incidence in the number of stillborns and atrophy of the testes and prostate and a decrease in pup body weight gain during lactation.**

Endpoint and dose for use in risk assessment: Reproductive NOEL = 10 mg/kg/day based on atrophy of the testes and prostate as well as an increase in the number of stillborns and a decrease in pup weight gain during lactation at 50 mg/kg/day (LOEL).

v. Chronic Occupational and Residential (Non-Cancer) {Several Months to Lifetime} [MRID Nos. 00149582, 00165247]

Male and female Sprague-Dawley rats were fed diets containing myclobutanil (91.4%) at 0, 25/35/ 50, 100/140/200 or 400/560/800 ppm (2 weeks/2 weeks/to termination) for 24 months. These dose levels corresponded to 0, 2.49, 9.84 or 39.21 mg/kg/day in males and 0, 3.23, 12.86, or 52.34 mg/kg/day in females. There was no evidence of carcinogenicity. For chronic toxicity the NOEL was 50 ppm (2.5 mg/kg/day and the LOEL was 200 ppm (10 mg/kg/day) based on decreased testicular weights and increased incidence of testicular atrophy.

Since an oral dose was identified, 100% dermal absorption should be used for risk assessments. The 100% dermal absorption is based on the lack of a dermal absorption study as well as the lack of comparative oral and dermal NOELs/LOELs in the same species to estimate a dermal absorption factor. This dose and endpoint was also used for chronic dietary risk assessment.

In general a risk assessment for inhalation exposure is not necessary for pesticides placed in Toxicity Category IV (i.e., low toxicity concern). Myclobutanil, based on the LC_{50} value of >5.1 mg/L is placed in Toxicity Category IV. However, because of the potential for exposure via this route, a risk assessment may be required.

Since only an acute inhalation toxicity study was available, the Committee recommended the use of oral NOELs for the inhalation exposure risk assessments. The doses identified for inhalation risk assessments are from oral studies (i.e., use of oral NOEL). Therefore, risk assessment should be as follows:

(i) The inhalation exposure component (i.e., mg/L) using a 100% absorption rate (default value) should be converted to a dose (mg/kg/day).

(ii) The dermal exposure component (i.e., mg/kg/day) using 100% dermal absorption may be combined with this converted dose (mg/kg/day).

(iii) This dose should then be compared to the oral NOELs of 10 mg/kg/day for Intermediate-Term exposure and 2.49 mg/kg/day for Long-Term exposures to calculate the Margins of Exposure.

3. Dietary Exposure and Risk Assessment/Characterization

a. Dietary Exposure (Food Sources)

i. Directions for Use (OPPTS GLN 860.1200)

Bananas

Spray, dip or run harvested bananas through a cascade system containing a 200-400 ppm solution of Systhane® 2E or Rally 40W for crown rot complex. Use 1 to 2 fluid ounces of Systhane® 2E (0.015 to 0.031 lbs. ai) per 10 gallons of water or use one or two 50-gram pouches of Rally 40W in 100 liters of water (0.044-0.088 lb ai in 26.4 gal water). Use the high label rate during periods of the year when crown rot problems are likely to be severe or when banana fruit will be in transit or storage for prolonged periods of time. Treatment is limited to a single application of a maximum of 400 ppm active ingredient. Application equipment should be adjusted to apply treatment throughout the cut banana hands, particularly to the crowns. In spray or cascade systems, freshly cut crowns should face the direction of the spray solution to assure thorough coverage of the cut crown. Treated bananas should be drip-dried prior to being packed for transportation and storage.

ii. Plant Metabolism (OPPTS 860.1300)

Wheat

Wheat plants (PP#4G3149) were grown under field conditions and treated with parent myclobutanil (RH-3866). RH-3866 is oxidized on the butyl chain to yield the alcohol, RH-9090 (free and bound). The alcohol metabolite [alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] is the major metabolite. The alcohol is further oxidized to the ketone, RH-9089 [alpha-(3-ketobutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile]. RH- 9089 comprises 2%-6% of the final residue. The nature of the residues in wheat were adequately defined. The residues of concern in wheat are the parent myclobutanil and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound).

Apples and Grapes

Apple and grape metabolism data were submitted in PP#7G3479 (R. Loranger, 6/16/87). Myclobutanil (RH-3866) is metabolized by hydroxylation of the number three carbon on the butyl chain, with

subsequent conjugation to form glucoside(s). Small amounts of the ketone (1%-3% of the whole fruit) are also present. Metabolism in grapes proceeds via the same pathway as in apples. The nature of the residues in apples and grapes were adequately defined. The residues of concern in apples and grapes are myclobutanil and the alcohol metabolite [alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] (free and bound).

A translocation study was conducted in support of PP#4G3149. A methanol solution of ^{14}C-labeled RH-3866 was applied to a single wheat blade and a single leaf of grape and apple seedlings. Plants were taken at various intervals, lyophilized and autoradiographed. For wheat, the treated blade, roots and remaining foliage were separately combusted to quantitate the extent of translocation. In a second study, seedlings were grown in nutrient solutions of ^{14}C-labeled RH-3866. These plants were also lyophilized and autoradiographed with some combustion to measure the extent of absorption and translocation. It was concluded from these studies that very little RH-3866 translocates beyond treated leaves following foliar application; however, when absorbed by roots, the fungicide translocates readily throughout the entire plant (R. Loranger's memo of 1/9/85).

Based on the three metabolism studies on wheat, apples and grapes [which indicate a similar metabolic route for crops in three different crop groups as defined in 40 CFR 180.41], the nature of the residue in bananas is adequately understood. The residues of concern in bananas are myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound).

iii. Animal Metabolism (OPPTS 860.1300)

The nature of the residue in animals is adequately understood. The residues of concern in animal commodities except milk are myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free). The residues of concern in milk are myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolites, alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) and alpha-(4-chlorophenyl)-alpha-(3,4-dihydroxybutyl)-1H-1,2,4-triazole-1-propanenitrile.

iv. Residue Analytical Method - Plants (OPPTS GLN 860.1340)

The enforcement method for plants is Method 34S-88-10 (MRID #408033-02). Method 34S-88-10 has been sent to FDA for inclusion in PAM II. Briefly, plant samples are extracted with 0.5 N HCl/MeOH either overnight or over a 6 hour period. This step converts RH-9090 conjugate residues to RH-9090. Extracted RH-9089 is converted to RH-9090 by $NaBH_4$ reduction. The extract is partially purified by petroleum ether partition, two methylene chloride partitions, Chelex-100-Fe^{+++} affinity chromatography, and fluorisil column chromatography. RH-3866 (RH-9090) quantification is performed by GLC with an N/P (ECD) detector. The sensitivity of the method (based on the EPA method validation on apples; PP#7F3476, M.J. Nelson, 7/18/89) is 0.1 ppm for parent and 0.2 ppm for its alcohol metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile.

An adequate enforcement method (Rohm and Haas Method 34S-88-10, MRID #408033-02) is available to enforce the proposed tolerance on bananas. Quantitation is by GLC using a nitrogen/phosphorus detector for parent myclobutanil and an electron capture detector (Ni^{63}) for residues measured as the alcohol metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile.

v. Residue Analytical Method - Animals (OPPTS GLN 860.1340)

Enforcement methods for the established tolerances on animal commodities are Methods 34S-88-22 (MRID #408253-01), 34S-88-15 (MRID #406458-01), 31S-87-02 (MRID #404813-01), and 34S-88-21 (MRID #408033-01). These methods have been submitted for publication in PAM II (PP#7F3476, M.J. Nelson, 7/18/89).

vi. Multiresidue Methods (OPPTS GLN 860.1360)

The FDA Pestrack data base (PAM Vol. I, Appendix, date 11/6/90) indicates that complete recovery has been obtained for myclobutanil under FDA multiresidue method D. Variable recovery has been obtained under FDA multiresidue method A under special instrument conditions. The alcohol metabolite, RH-9090, has a variable recovery under FDA multiresidue method A under special instrument conditions.

vii. Storage Stability (OPPTS GLN 860.1380)

Storage stability studies for myclobutanil on apples (Rohm and Haas Technical Report #31H-86-04, Accession #266109) and grapes (Rohm and Haas Technical Report #31H-86-06, Accession #266115)

have been reviewed (PP#7F3476, M.J. Nelson, 2/8/88). Rohm and Haas was the performing lab for both studies. In another submission (PP#7F3476, M.J. Nelson, 4/26/88), apples and grapes were reanalyzed for RH-3866 and RH-9090 after frozen storage. The storage stability data discussed in the M.J. Nelson reviews dated 2/8/88 and 4/26/88 were summarized (PP#9F3811, W.T. Chin, 8/2/90) as follows: "Apples and grapes fortified with RH-3866 and stored up to 2 years yielded recoveries between 84% and 108%. Grapes and apples treated with RH-3866, harvested, analyzed, and stored over 3 years and reanalyzed for both RH-3866 and RH-9090 showed no change in the levels or composition of the residues demonstrating the long-term stability of myclobutanil and RH-9090. These data indicate that myclobutanil residues are stable in samples for at least 3 years under frozen conditions."

Adequate storage stability data are available on grapes and apples. Residues of myclobutanil and RH-9090 will be stable on grapes and apples for at least 24 months. Since grapes, apples, and bananas are all fruits, the storage stability data on grapes and apples can be translated to bananas.

viii. Magnitude of the Residue in Water, Fish, and Irrigated Crops (OPPTS GLN 860.1400)

Myclobutanil is not registered for direct use on potable water or aquatic food and feed crops; therefore, no residue chemistry data are required under these guideline topics.

ix. Food Handling Establishments (OPPTS GLN 860.1460)

Myclobutanil is not registered for use in food-handling establishments; therefore, no residue chemistry data are required under this guideline topic.

x. Magnitude of the Residue in Meat, Milk, Poultry, and Eggs (OPPTS GLN 860.1480)

Meat, milk, poultry and egg tolerances have been established (40 CFR 180.443).

Since no animal feed items are associated with bananas, residues will not occur in animal commodities as a result of the proposed use of myclobutanil on bananas.

xi. Magnitude of the Residue in Crop Field Trials (OPPTS GLN 860.1500)

"Post Harvest Residue Study on Bananas Treated with Myclobutanil, RAR 91-0011, 91-0012, 91-0013, 91-0014"; W. J. Zogorski, N. Ding; 2/28/92; Laboratory Project ID Rohm and Haas Analytical Report

No. 34A-92-02. Performing laboratories were Del Monte USA Research Center, Walnut Creek, CA and Rohm and Haas Company, Spring House, PA (MRID #424459-01).

Four trials were conducted during 1991 in California. The petitioner notes that treatment of bananas with myclobutanil would normally occur in the country of origin, but there are no treatment stations in the banana exporting countries with facilities which could comply with US EPA GLP requirements, nor are there laboratories with the requisite level of analytical documentation to comply with the GLP requirements. Therefore, the residue trials would be conducted at US facilities. All cold room storage, gasification, sample collection, separation of peel and pulp, and processing for analyses for the four trials took place at Del Monte USA Research Center, Walnut Creek, CA. In trials #1 and #3, myclobutanil was applied as a spray treatment to banana hands at the rates of 200 ppm (0.5X), 400 ppm (1X), and 800 ppm (2X). In trial #2, myclobutanil was applied as a dip treatment to banana hands at the rate of 200 ppm (0.5X), 400 ppm (1X), and 800 ppm (2X). Trial #4 was a comparison between the spray and dip treatments each made at the rates of 200 ppm (0.5X) and 400 ppm (1X). The petitioner stated that all banana treatments consisted of one application of myclobutanil. Prior to myclobutanil application, fresh cuts of banana hands (8 to 10 bananas) obtained from Del Monte as received at the port of entry, were passed through a 15 L tank containing a solution of clear water and 1% alum (the petitioner claims that banana companies use this solution as an astringent to reduce latex bleed, and consequently fruit staining) and allowed to drip dry for 2 to 3 minutes. After myclobutanil application, banana hands were allowed to dry for one hour before being placed in commercial banana plastic storage bags, placed in cardboard banana boxes and placed in a cold room maintained at 13°C ± 1°C for specified holding periods of 7, 14, and 21 days after treatment. All 0 day samples were collected immediately after myclobutanil application and air drying; these banana samples are in the green state without gasification or supermarket shelf storage time.

The lack of residue data from the countries where use is intended is not a major concern here because the use is for postharvest application; environmental factors affecting residues on a growing crop are not a concern here.

The bananas were removed from the cold room at the appropriate time intervals and transferred to a cold room maintained at 17°C ± 1°C where they were exposed to ethylene gas for 24 hours (this procedure is called the ripening procedure). The bananas were held in the cold room (without ethylene gas) for 3 days to simulate supermarket shelf storage. After this storage period, the bananas were separated into peel and pulp, homogenized in a

food processor with dry ice, and allowed to set unsealed in frozen storage for 24 hours (to allow CO_2 escape). After this procedure, they were sealed and frozen at -23°C until analysis. Bananas were analyzed within 30 days of sampling. The average time from extraction to analysis was 10 days. Extracts were stored frozen at -5°C to -25°C.

Recovery data were obtained from untreated samples of bananas fortified with RH-3866 at the levels of 0.01 ppm, 0.02 ppm, 0.05 ppm, 0.2 ppm, 1.0 ppm, and 10 ppm prior to extraction. Recovery values ranged from 73% to 129% for fortification level of 0.01 ppm; 73.9% to 125% for fortification level of 0.02 ppm; 59.9% to 115% for fortification level of 0.05 ppm; 76.6% to 85.6% for fortification level of 0.2 ppm; 78.1% to 92.8% for fortification level of 1.0 ppm; and 79% to 90% for fortification level of 10 ppm. Recovery data were obtained from untreated samples of bananas fortified with RH-9090 at the levels of 0.01 ppm, 0.02 ppm, 0.05 ppm, 0.20 ppm, 1.0 ppm, and 10 ppm. Recovery values ranged from 73.7% to 133% for fortification level of 0.01 ppm; 73.5% to 105% for fortification level of 0.02 ppm; 73.6% to 108% for fortification level of 0.05 ppm; 53.7% to 78% for fortification level of 0.20 ppm; 59.4% to 63.4% for fortification level of 1.0 ppm; and 53.4% to 65.6% for fortification level of 10 ppm.

Residues were corrected for the average fortification recoveries based on Rohm and Haas in-house 1990 and 1991 stone fruit analyses: 90% for RH-3866 and 85% for RH-9090. Those stone fruit recoveries were comparable to average banana recoveries obtained during the CA study, which were 93% for RH-3866 and 82% for RH-9090 as shown in the following table:

TABLE 16. PROCEDURAL PERCENT RECOVERY DATA for RAR #'s 91-0011, 91-0012, 91-0013, and 91-0014 (MRID #424459-01)

RH-3866 in Banana Peel	RH-3866 in Banana Pulp	RH-9090 in Banana Peel	RH-9090 in Banana Pulp
73.9-125 (av. 86.42)	59.9-129 (av. 100.39)	53.4-105 (av. 70.08)	73.6-133 (av. 94.61)
average RH-3866: 93		average RH-9090: 82	

Table 17 summarizes the amount of residues on bananas in the four CA studies resulting from post-harvest treatment of myclobutanil.

Table 17. Myclobutanil Residues on Bananas

Trial ID#	Application Rate	Sample Description	Treatment to Sampling Interval (days)	RH-3866 (ppm)	RH-9090 (ppm)	Total Residue (ppm)[a]
91-0011[b]						
	200 ppm (0.5X)	peel and pulp	0	0.36	0.01	0.37
		peel and pulp	7	0.30	0.01	0.31
		peel and pulp	14	0.35	0.01	0.36
		peel and pulp	21	0.02	0.03	0.05
	400 ppm (1X)	peel and pulp	0	0.36	0.01	0.37
		peel and pulp	7	0.53	0.01	0.54
		peel and pulp	14	0.36	0.03	0.39
		peel and pulp	21	0.85	0.02	0.87
	800 ppm (2X)	peel and pulp	0	0.03	0.01	0.04
		peel and pulp	7	0.67	0.01	0.68
		peel and pulp	14	0.17	0.004	0.17
		peel and pulp	21	0.09	ND	0.09
	200 ppm (0.5X)	pulp only	0	ND	ND	ND
		pulp only	7	0.01	ND	0.01
		pulp only	14	0.02	ND	0.02
		pulp only	21	0.02	ND	0.02
	400 ppm (1X)	pulp only	0	ND	ND	ND

Trial ID#	Application Rate	Sample Description	Treatment to Sampling Interval (days)	RH-3866 (ppm)	RH-9090 (ppm)	Total Residue (ppm)[a]
		pulp only	7	0.02	ND	0.02
		pulp only	14	0.02	0.01	0.03
		pulp only	21	0.03	0.004	0.03
	800 ppm (2X)	pulp only	0	ND	ND	ND
		pulp only	7	0.01	ND	0.01
		pulp only	14	0.02	0.004	0.02
		pulp only	21	ND	ND	ND
91-0012[c]						
	200 ppm (0.5X)	pulp and peel	0	1.08	0.01	1.09
		pulp and peel	7	1.17	0.10	1.27
		pulp and peel	14	1.13	0.10	1.23
		pulp and peel	21	1.65	0.04	1.69
	400 ppm (1X)	pulp and peel	0	1.64	0.01	1.65
		pulp and peel	7	2.11	0.09	2.20
		pulp and peel	14	2.39	0.08	2.47
		pulp and peel	21	2.54	0.06	2.60
	800 ppm (2X)	pulp and peel	0	3.01	ND	3.01
		pulp and peel	7	3.87	0.05	3.92
		pulp and peel	14	3.30	0.08	3.38
		pulp and peel	21	4.73	0.02	4.75

Trial ID#	Application Rate	Sample Description	Treatment to Sampling Interval (days)	RH-3866 (ppm)	RH-9090 (ppm)	Total Residue (ppm)[a]
	200 ppm (0.5X)	pulp only	0	ND	ND	ND
		pulp only	7	0.03	0.01	0.04
		pulp only	14	0.03	0.01	0.03
		pulp only	21	0.07	0.01	0.08
	400 ppm (1X)	pulp only	0	ND	ND	ND
		pulp only	7	0.05	0.02	0.07
		pulp only	14	0.06	0.01	0.07
		pulp only	21	ND	0.01	0.01
	800 ppm (2X)	pulp only	0	ND	ND	ND
		pulp only	7	0.11	0.03	0.14
		pulp only	14	0.09	0.02	0.11
		pulp only	21	0.14	0.01	0.15
91-0013[b]						
	200 ppm (0.5X)	pulp and peel	0	0.13	ND	0.13
		pulp and peel	7	0.22	0.01	0.23
		pulp and peel	14	0.41	0.01	0.42
		pulp and peel	21	0.36	0.01	0.37
	400 ppm (1X)	pulp and peel	0	0.28	0.01	0.29
		pulp and peel	7	0.59	0.03	0.62
		pulp and peel	14	0.63	0.03	0.66
		pulp and peel	21	0.74	0.01	0.75

Trial ID#	Application Rate	Sample Description	Treatment to Sampling Interval (days)	RH-3866 (ppm)	RH-9090 (ppm)	Total Residue (ppm)[a]
	800 ppm (2X)	pulp and peel	0	0.04	0.01	0.05
		pulp and peel	7	0.21	0.02	0.23
		pulp and peel	14	0.62	0.03	0.65
		pulp and peel	21	0.68	0.01	0.69
	200 ppm (0.5X)	pulp only	0	ND	ND	ND
		pulp only	7	0.02	ND	0.02
		pulp only	14	ND	ND	ND
		pulp only	21	ND	ND	ND
	400 ppm (1X)	pulp only	0	ND	ND	ND
		pulp only	7	0.02	0.01	0.03
		pulp only	14	0.03	0.01	0.04
		pulp only	21	0.02	ND	0.02
	800 ppm (2X)	pulp only	0	ND	ND	ND
		pulp only	7	0.02	0.01	0.03
		pulp only	14	0.02	0.01	0.03
		pulp only	21	0.02	ND	0.02
91-0014						
	200 ppm (0.5X)[b]	pulp and peel	0	0.03	ND	0.03
		pulp and peel	7	0.02	ND	0.02

Trial ID#	Application Rate	Sample Description	Treatment to Sampling Interval (days)	RH-3866 (ppm)	RH-9090 (ppm)	Total Residue (ppm)[a]
		pulp and peel	14	0.03	0.01	0.04
		pulp and peel	21	0.02	ND	0.02
	400 ppm (1X)[b]	pulp and peel	0	ND	ND	ND
		pulp and peel	7	0.02	ND	0.02
		pulp and peel	14	0.07	ND	0.07
		pulp and peel	21	0.12	ND	0.12
	200 ppm (0.5X)[c]	pulp and peel	0	0.67	0.01	0.68
		pulp and peel	7	0.95	0.02	0.97
		pulp and peel	14	1.15	0.02	1.17
		pulp and peel	21	1.03	0.02	1.05
	400 ppm (1X)[c]	pulp and peel	0	1.33	0.01	1.34
		pulp and peel	7	1.72	0.03	1.75
		pulp and peel	14	1.65	0.03	1.68
		pulp and peel	21	1.49	0.04	1.53
	200 ppm (0.5X)[b]	pulp only	0	0.01	ND	0.01
		pulp only	7	ND	ND	ND
		pulp only	14	ND	0.01	0.01
		pulp only	21	ND	ND	ND

Trial ID#	Application Rate	Sample Description	Treatment to Sampling Interval (days)	RH-3866 (ppm)	RH-9090 (ppm)	Total Residue (ppm)[a]
	400 ppm (1X)[b]	pulp only	0	ND	ND	ND
		pulp only	7	0.02	ND	0.02
		pulp only	14	0.01	ND	0.01
		pulp only	21	0.01	ND	0.01
	200 ppm (0.5X)[c]	pulp only	0	ND	ND	ND
		pulp only	7	0.03	0.01	0.04
		pulp only	14	0.03	ND	0.03
		pulp only	21	0.03	ND	0.03
	400 ppm (1X)[c]	pulp only	0	0.01	ND	0.01
		pulp only	7	0.01	0.01	0.02
		pulp only	14	0.04	0.01	0.05
		pulp only	21	0.05	0.01	0.06

a - Total residue includes RH-3866, RH-9090, RH-9090 conjugates, and RH-9089.
b - Hand spray treatment.
c - Hand dipped treatment.

The CA residue data indicate that the highest residue values were from the samples that received the dip treatment. The highest value on banana peel treated at the 1X rate (400 ppm) was 2.60 and 4.60 ppm for the 2X (800 ppm) treatment. Residue data on bananas show that the highest residue obtained after the 1X (400 ppm) treatment were 2.60 ppm for samples of peel and pulp; and 0.07 ppm for samples of pulp only. The highest residue obtained after the 2X (800 ppm) treatment were 4.75 ppm for samples of peel and pulp; and 0.15 ppm for samples of pulp only. The highest residue value obtained after the 0.5X (200 ppm) treatment were of 1.69 ppm for peel and pulp and 0.08 for pulp only. The petitioner claims that the apparent increase in myclobutanil residues found in bananas are due to the natural loss of moisture from the fruit over time.

Four additional postharvest residue studies on bananas were conducted in HI (MRID #430160-01, Rohm and Haas Analytical Report No. 34A-93-13, RAR 92-0061, 92-0062, 92-0063, and 92-0064). Systhane 2E Fungicide (707-EEE) and Rally 40W (707-215) were applied to compare residues from the two formulations. Residues from two application modes (spraying and dipping) were also compared. The performing laboratories were Del Monte USA Research Center, Walnut Creek, CA; Rohm and Haas Company, Spring House, PA; and Research Designed for Agriculture, RDA, a Division of West Consulting, Yuma, AZ.

Green bananas were harvested, cut into hands of 4-6 fingers, washed, and drip dried. The bananas were then treated once with a myclobutanil solution by dipping or spraying as follows:

Dipping- The banana hands were submerged for 2-3 seconds in a 5 gallon bucket containing the aqueous myclobutanil solution and 1% alum. After dipping, the bananas were air dried for 3-7 minutes.

Spraying- The green banana hands were arranged on trays so that the crowns faced the spray nozzle. The aqueous myclobutanil solution containing 1% alum was applied using a handgun calibrated to deliver 0.5 liters spray to each tray. After spraying, the bananas were air dried for 3-7 minutes.

The treatment types, rates, and ai applied in the four studies are tabulated as follows:

Table 18. Trial #1. Valery Banana Company, Kurtistown, HI

Treatment #	Treatment Type	Rate	ai applied (ppm)
#1	Control	0	0
#2	Systhane 2E Spray	0.5X	200 ± 10
#3	Systhane 2E Spray	1X	400 ± 20
#4	Systhane 2E Spray	2X	800 ± 20

Table 19. Trial #2. Keaau Plantation, Inc., Hilo, HI

Treatment #	Treatment Type	Rate	ai applied (ppm)
#1	Control	0	0
#2	Systhane 2E Dip	0.5X	200 ± 10
#3	Systhane 2E Dip	1X	400 ± 20
#4	Systhane 2E Spray	1X	400 ± 20
#5	Rally 40W Spray	1X	400 ± 20
#6	Rally 40W Dip	1X	400 ± 20

Table 20. Trial #3. Keaau Plantation, Inc., Hilo, HI

Treatment #	Treatment Type	Rate	ai applied (ppm)
#1	Control	0	0
#2	Systhane 2E Spray	1X	400 ± 20
#3	Systhane 2E Spray	2X	800 ± 40
#4	Rally 40W Spray	1X	400 ± 20
#5	Rally 40W Spray	2X	800 ± 40

Table 21. Trial #4. Robert Ha Inc., Hilo, HI			
Treatment #	Treatment Type	Rate	ai applied (ppm)
#1	Control	0	0
#2	Systhane 2E Spray	0.5X	200 ± 10
#3	Systhane 2E Spray	1X	400 ± 20
#4	Rally 40W Spray	1X	400 ± 20

After dipping or spraying, the banana hands were placed in plastic storage bags. The bags were placed in cardboard shipping boxes. The boxes were transported overnight to DelMonte USA Research Center, CA for analyses. All but the zero day samples were stored in a 13°C humidity controlled chambe to await ethylene treatment at the appropriate time.

The treatment to sampling intervals were 0, 7, 14, 21, and 28 days. The 0-day samples were analyzed within 24 hours of application without treatment with ethylene. The other samples were taken from the cold room at 3, 10, 17, and 24 days after treatment with myclobutanil and treated with ethylene (approx. 1000-1400 ppm ethylene gas concentration, 17°C, ambient humidity) for 24 hours to attain color stage #3. The samples were held for 3 days in cold storage (17°C) to simulate supermarket shelf storage to attain color stage #4.

The whole bananas were weighed, separated into peel and pulp, and the pulp was weighed. Each sample was separately homogenized with dry ice; allowed to sit in unsealed plastic bags in frozen storage for 24 hours to allow the CO_2 to escape, and then sealed and stored frozen (-10°C) until the date of analyses. Residues in the whole banana were calculated using weights of the peel and whole banana and measured residues in the peel and pulp using the following calculation:

$$\text{residues in banana} = \frac{\text{weight of peel}}{\text{weight of banana}} \times \text{residues in peel} + \frac{\text{weight of pulp}}{\text{weight of banana}} \times \text{residues in pulp}$$

Residues were determined in the pulp and peel using TR 34S-88-10. The method determines RH-3866 and compounds converted to RH-9090 by the analytical method (ie. RH-9090, RH-9089, and RH-9090 glycoside conjugates). As stated by the petitioner, "residues

were corrected for the average fortification recoveries based on Rohm and Haas in-house 1990 and 1991 stone fruit analysis and earlier run banana analyses (Rohm and Haas Analytical Report #34A-92-02) and which were found to be comparable to banana recoveries obtained during this study: 85% for RH-3866 in peel, 85% for RH-3866 in pulp, 75% for RH-9090 in peel, and 80% for RH-9090 in pulp." Both uncorrected and corrected residue values were included in MRID #430160-01. Corrected values are reported in the tables below. Residues of 3866 were corrected for 85% recovery. Residues of 9090 were corrected for 75% recovery.

Actual recoveries for the four studies in HI were reported and are tabulated below:

Table 22. Recoveries from HI Studies

Study #	Matrix	Fortification (ppm RH-3866)	% Recoveries of RH-3866	Fortification (ppm RH-9090)	% Recoveries of RH-9090
92-0061	peel	0.02-10.9	69.6-96.2 (av. 84.4)	0.02-0.50	59.2-95.0 (av. 77.6)
	pulp	0.02-1.0	69.8-103.0 (av. 83.5)	0.02-0.1	65.9-102.0 (av. 81.4)
92-0062	peel	0.02-10.9	77.4-87.5 (av. 82.4)	0.02-0.5	69.4-79.9 (av. 74.6)
	pulp	---	---	---	---
92-0063	peel	0.02-10.9	86.4-103.0 (av. 92.3)	0.02-0.5	63.9-81.9 (av. 74.0)
	pulp	0.02-0.4	73.4-97.4 (av. 85.6)	0.02-0.1	70.9-109.0 (av. 83.9)
92-0064	peel	---	---	---	---
	pulp	0.02-0.4	98.6-109.0 (av. 103.8)	0.02-0.1	87.5-178.0 (av. 132.8)

Residue data are reported below:

TABLE 23. RESIDUES IN BANANA PEEL AT 20C PPM AI APPLICATION RATE					
FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
2E/spray	92-0061	0	1.02	NDR	1.02
		7	1.14	0.0305	1.17
		14	1.14	0.0356	1.18
		21	1.28	0.0400	1.32
		28	1.16	0.0416	1.21
2E/dip	92-0062	0	1.34	NDR	1.34
		14	1.14	0.0424	1.18
		28	0.978	0.0784	1.06
2E/spray	92-0064	0	1.25	NDR	1.25
		14	1.58	0.0476	1.62
		28	1.10	0.0452	1.14

TABLE 24. RESIDUES IN BANANA PEEL AT 400 PPM AI APPLICATION RATE					
FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
2E/spray	92-0061	0	1.93	0.0088	1.94
		7	2.21	0.0600	2.27
		14	1.76	0.0604	1.82
		21	2.25	0.0840	2.33
		28	1.99	0.0768	2.07
2E/dip	92-0062	0	2.04	0.0115	2.05
		14	1.94	0.0636	2.00
		28	1.53	0.0908	1.62
2E/spray	92-0062	0	2.56	0.0111	2.57
		14	2.27	0.0736	2.34
		28	3.65	0.1240	3.77

TABLE 25. RESIDUES IN BANANA PEEL AT 400 PPM AI APPLICATION RATE					
FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
40W/spray	92-0062	0	1.32	NDR	1.32
		14	1.38	0.0604	1.44
		28	1.48	0.0748	1.56
40W/dip	92-0062	0	1.58	0.0083	1.59
		14	1.27	0.0552	1.32
		28	1.60	0.0664	1.67
2E/spray	92-0063	0	2.26	NDR	2.26
		7	2.72	0.0275	2.75
		14	2.08	0.046	2.13
		21	2.84	0.0616	2.90
		28	2.58	0.0748	2.65

TABLE 26. RESIDUES IN BANANA PEEL AT 400 PPM AI APPLICATION RATE

FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
40W/spray	92-0063	0	1.56	NDR	1.56
		14	1.45	0.0544	1.50
		28	1.67	0.0540	1.72
2E/spray	92-0064	0	2.72	0.0109	2.73
		14	2.26	0.0656	2.32
		28	3.24	0.1100	3.35
40W/spray	92-0064	0	1.79	NDR	1.79
		14	2.33	0.0638	2.39
		28	2.67	0.0844	2.75

TABLE 27. RESIDUES IN BANANA PEEL AT 800 PPM AI APPLICATION RATE

FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
2E/spray	92-0061	0	5.18	0.013	5.19
		7	4.92	0.0834	5.00
		14	4.20	0.0788	4.28
		21	4.05	0.126	4.18
		28	3.69	0.143	3.83
2E/spray	92-0063	0	4.93	0.012	4.94
		7	6.94	0.0524	6.99
		14	4.93	0.0752	5.00
		21	5.74	0.107	5.85
		28	5.60	0.104	5.70

TABLE 27. RESIDUES IN BANANA PEEL AT 800 PPM AI APPLICATION RATE					
FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
40W/spray	92-0063	0	1.96	0.004	1.96
		14	3.33	0.0608	3.39
		28	2.88	0.0896	2.97

TABLE 28. RESIDUES IN BANANA PULP AT 200 PPM AI APPLICATION RATE					
FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
2E/spray	92-0061	0	0.012	0.0000	0.012
		7	0.0875	NDR	0.0875
		14	0.107	NDR	0.107
		21	0.0889	0.0533	0.142
		28	0.0681	0.0369	0.105
2E/dip	92-0062	0	0.0244	0.0000	0.0244
		14	0.113	NDR	0.113
		28	0.174	0.0181	0.192
2E/spray	92-0064	0	0.0184	0.0000	0.0184
		14	0.136	0.0117	0.148
		28	0.0776	0.0345	0.112

TABLE 29. RESIDUES IN BANANA PULP AT 400 PPM AI APPLICATION RATE					
FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
2E/spray	92-0061	0	0.0301	0.0000	0.0301
		7	0.186	0.0119	0.198
		14	0.189	0.0158	0.205
		21	0.219	0.0615	0.280
		28	0.165	0.0683	0.233
2E/dip	92-0062	0	0.0286	NDR	0.0286
		14	0.209	0.0098	0.219
		28	0.195	0.0750	0.270
2E/spray	92-0062	0	0.0459	0.0000	0.0459
		14	0.253	0.0131	0.266
		28	0.274	0.0476	0.322

TABLE 30. RESIDUES IN BANANA PULP AT 400 PPM AI APPLICATION RATE

FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
40W/spray	92-0062	0	0.0239	0.0000	0.0239
		14	0.205	0.0145	0.22
		28	0.178	0.0413	0.22
40W/dip	92-0062	0	0.0266	0.0000	0.0266
		14	0.166	0.0298	0.196
		28	0.116	0.0248	0.141
2E/spray	92-0063	0	0.0199	NDR	0.0199
		7	0.0999	NDR	0.0999
		14	0.126	0.0087	0.135
		21	0.167	0.0154	0.182
		28	0.148	0.025[illegible]	0.174

TABLE 31. RESIDUES IN BANANA PULP AT 400 PPM AI APPLICATION RATE

FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
40W/spray	92-0063	0	0.0184	0.0000	0.0184
		14	0.188	0.0104	0.198
		28	0.1009	0.0192	0.120
2E/spray	92-0064	0	0.042	0.0000	0.042
		14	0.221	0.0167	0.238
		28	0.277	0.0328	0.310
40W/spray	92-0064	0	0.0305	0.0000	0.0305
		14	0.213	0.0338	0.247

TABLE 31. RESIDUES IN BANANA PULP AT 400 PPM AI APPLICATION RATE					
FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
		28	0.411	0.0360	0.447

TABLE 32. RESIDUES IN BANANA PULP AT 800 PPM AI APPLICATION RATE					
FORMULATION/ APPLICATION	STUDY #	TSI	RH-3866 (ppm)	RH-9090 (ppm)	TOTAL RESIDUES (ppm)
2E/spray	92-0061	0	0.0324	0.0000	0.0324
		7	0.256	0.0186	0.275
		14	0.327	0.0268	0.354
		21	0.471	0.0893	0.560
		28	0.301	0.0450	0.346
2E/spray	92-0063	0	0.0446	0.0000	0.0446
		7	0.228	NDR	0.228
		14	0.266	0.0155	0.282
		21	0.316	0.0272	0.343
		28	0.280	0.0275	0.308
40W/spray	92-0063	0	0.0282	0.0000	0.0282
		14	0.239	0.0144	0.253
		28	0.235	0.0321	0.267

TABLE 33. SUMMARY OF RESIDUES IN PEEL, PULP, AND WHOLE BANANA			
APPL. RATE (ppm)	RESIDUES IN PEEL (ppm)	RESIDUES IN PULP (ppm)	RESIDUES IN WHOLE BANANA (ppm)
200	1.02-1.62 av. 1.23	0.012-0.192 av. 0.0975	0.43-0.69 av. 0.54
400	1.32-3.77 av. 2.15	0.0184-0.447 av. 0.1677	0.60-1.36 av. 0.94
800	1.97-6.99 av. 4.56	0.0282-0.56 av. 0.256	0.92-3.10 av. 2.00

Storage conditions for bananas in the HI study (MRID #430160-01) were described as follows:

"After Myclobutanil treatment of the bananas, the bananas were placed in a cold room maintained at 13°C ± 1°C for specified holding periods of 3, 10, 17, and 24 days after treatment. The bananas were removed from the 13°C cold room at the appropriate time interval and transferred to a cold room maintained at 17°C ± 1°C where they were exposed to ethylene gas for 24 hours. The bananas were then held in the cold room (without ethylene gas) for 3 days to simulate supermarket shelf storage. Bananas were then separated into pulp and peel, chopped with dry ice to a homogenous mass and immediately frozen until analysis. All sample extracts, either interim or final, were stored in a freezer (with temperatures ranging from -5°C to -25°C)."

With one exception, the time from extraction to analysis for the HI banana samples was 2-13 days.

The combined residues of myclobutanil [alpha-butyl-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile] and its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile (free and bound) resulting from the proposed use will not exceed 4.0 ppm in bananas. (Note: The tolerance on bananas is for the raw agricultural commodity as defined in 40 CFR 180.1(j)(1). Both peel and pulp are included. Crown tissue or stalk are excluded.)

For risk assessment purposes only, HED concludes that residues resulting from the proposed use will not exceed 0.8 ppm in banana pulp.

xii. Magnitude of the Residue in Processed Food/Feed (OPPTS GLN 860.1520)

There are no processed commodities associated with bananas.

xiii. Confined Accumulation in Rotational Crops (OPPTS GLN 860.1850)

Rotational crop studies are not required for uses of pesticides on bananas.

xiv. Field Accumulation in Rotational Crops (OPPTS GLN 860.1900)

Rotational crop studies are not required for uses of pesticides on bananas.

xv. Reduction of the Residues - Anticipated Residues

Not applicable.

xvi. Codex Harmonization

There are no Codex, Canadian or Mexican residue limits established for myclobutanil and its metabolites on bananas. Therefore, no compatibility problems exist for the proposed tolerance on bananas.

b. Dietary Exposure - Drinking Water

Based on information in the EFED One Liner Database (updated: 12/20/94), myclobutanil is persistent and not considered mobile in soils with the exception of sandy soils. Data are not available for its metabolite alpha-(3-hydroxybutyl)-alpha-(4-chlorophenyl)-1H-1,2,4-triazole-1-propanenitrile. There is no established Maximum Contaminant Level for residues of myclobutanil in drinking water (Safe Drinking Water Hotline - personal communication 5/14/97). No Health Advisory Levels for myclobutanil in drinking water have been established. The "Pesticides in Groundwater Database" (EPA 734-12-92-001, September 1992) has no information concerning myclobutanil.

The Environmental Fate and Effects Division (D239591, Douglas Urban, 11/4/97) has provided estimates of ground and surface water concentrations for myclobutanil based on the label rate of 0.65 lbs a.i./acre and assuming 15 applications per season. (The action was for an import tolerance for bananas; the water numbers were based on turf.) The surface water numbers are based on the results of GENEEC model run. The ground water numbers are based on a screening tool, SCI-GROW, which tends to overestimate the true concentrations in the environment.

Surface water EEC [based on the results of a GENEEC Version 1.2, 5/3/95) model run]

Acute = 145.96 ppb (0.14596 ppm or mg/L)(maximum initial concentration)

Chronic = 118.6 ppb (0.1186 ppm or mg/L)(average 56-day concentration)

Note: OPP policy allows the 90/56-day GENEEC value to be divided by 3 to obtain a value for chronic risk assessment calculations. Therefore, the surface water value for use in the chronic risk assessment would be 0.04 ppm or mg/L.

Groundwater EEC (SCI-GROW, Lotus 1-2-3 spreadsheet)3.6 ppb (0.0036 ppm or mg/L) (use for both acute and chronic)

Chronic exposure from surface water is calculated below. Chronic exposure from ground water is lower.

Note: Exposure (mg/kg/day) = concentration in water in mg/L x 2 L water/day for males or females or 1 L water/day for children ÷ 70 kg for adult males or 60 kg for adult females or 10 kg for children

chronic exposure from surface water for adult males =
0.04 mg/L x 2 L/day ÷ 70 kg = 1.1×10^{-3} mg/kg/day

chronic exposure from surface water for adult females =
0.04 mg/L x 2 L/day ÷ 60 kg = 1.3×10^{-3} mg/kg/day

chronic exposure from surface water for children =
0.04 mg/L x 1 L/day ÷ 10 kg = 4.0×10^{-3} mg/kg/day

c. Dietary (Food and Water) Risk Assessment and Characterization

i. Chronic Risk (ARC)

In conducting this chronic dietary (food only) risk assessment, EPA has made somewhat conservative assumptions. With the exceptions of bananas for which a level representing residues in pulp rather than the whole banana was used and selected commodities which were corrected for percent crop treated, all commodities having myclobutanil tolerances will contain myclobutanil and metabolite residues and those residues will be at the level of the established tolerance. This results in an overestimate of human dietary exposure. For bananas, the level of 0.8 ppm was used in the dietary risk assessment rather than the proposed tolerance of 4.0 on bananas since residues in the pulp will not exceed 0.8 ppm. Percent crop-treated estimates were utilized for selected commodities included in the assessment. Thus, in making a safety determination for this tolerance, EPA is taking into account this partially refined exposure assessment.

Section 408(b)(2)(F) requires that if a tolerance relies on percent crop-treated data that the Agency make a determination as to the reliability of the data. Percent crop-treated estimates are derived from federal and private market survey data.

Typically, a range is assumed for the exposure assessment. By using this upper end estimate of percent crop treated, the Agency is reasonably certain that exposure is not understated for any significant population sub-group. Additionally, the DRES (Dietary Risk Evaluation System) modeling used in estimating chronic dietary risk uses regional consumption information to estimate exposure for four population sub-groups that are geographically based regions of the United States. None of these sub-groups exceeded the Agency's level of concern. To provide for the periodic evaluation of these estimates of percent crop treated, the Agency will require under Section 408(b)(2)(F) percent crop treated data to be submitted every 5 years as long as the tolerances remain in force.

The existing myclobutanil tolerances (published, pending, and including the necessary Section 18 tolerances) for crops other than bananas and the anticipated residues on bananas result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Population Subgroup	ARC_{food} (mg/kg/day)	%RfD
U.S. Population (48 states)	0.004255	17%
Nursing Infants (<1 year old)	0.006359	25%
Non-Nursing Infants(<1 yr old)	0.018836	75%
Children (1-6 years old)	0.011492	46%
Children (7-12 years old)	0.006910	28%
Northeast Region	0.004539	18%
Western Region	0.004848	19%
Hispanics	0.005049	20%
Non-Hispanic Others	0.004425	18%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

ii. Carcinogenic Risk

None. Myclobutanil is classified as Category E: not carcinogenic in animal studies.

iii. Acute Dietary Risk

The Toxicology Endpoint Selection Committee (TESC) did not identify an acute dietary toxicological endpoint and stated that an acute dietary risk assessment is not required (7/12/94).

iv. Drinking Water Risk - Chronic (non-cancer)

Chronic risk (non-cancer) from surface water is calculated below. The risk from ground water would be lower.

Note: Chronic risk (non-cancer) = exposure (mg/kg/day) ÷ RfD (mg/kg/day) x 100 = % RfD

chronic risk (non-cancer) from water (males) = $1.1 \times 10^{-3} \div 0.025$ mg/kg/day x 100 = 4.4% RfD

chronic risk (non-cancer) from water (females) = $1.3 \times 10^{-3} \div 0.025$ mg/kg/day x 100 = 5.2% RfD

chronic risk (non-cancer) from water (children) = $4.0 \times 10^{-3} \div 0.025$ mg/kg/day x 100 = 16% RfD

4. Occupational and Residential Exposure and Risk Assessment/Characterization

There is no occupational exposure in the U.S.A. as a result of the use on imported bananas. An occupational exposure assessment is not required for this petition.

Myclobutanil is currently registered for outdoor residential lawn and garden uses and greenhouse use on annuals and perennials, turf, shrubs, trees, and flowers (Reference Files System/OPP LAN, date searched: 6/5/97).

NOTE: This occupational/residential exposure assessment and risk estimate for myclobutanil supersedes the prior HED memo dated 25-NOV-1997. The following changes were included in order to refine the residential risk estimates:

- HED concluded that residential intermediate-term exposure is not expected for handlers or persons re-entering treated areas. Fungicide use on home lawns is limited, restricted to certain parts of the country, and considered to be a "rare, extra treatment" in homeowner Do-It-Yourself programs (Professional Lawn Care Association of America). The end-point selected for short-term risk assessment is from a 28-Day Dermal study in rats; this dosing duration is expected to adequately reflect the typical human exposures for this use.
- Maximum application rates are calculated from the use directions on the label: 0.76 lbs. a.i. handled per acre for the soluble concentrate; and 0.4 lbs. a.i. handled per acre for the granular formulation. Typical lawn size of 13,000 ft^2 is used in place of the high-end lawn default value of 20,000 ft^2. Postapplication exposure estimates assume that 10% of the application rate is available as dislodgeable residue since the label states that the product is not washed away by rain or sprinklers.

Currently there is no use/usage information source available to HED for residential end-use products. Therefore pertinent information is unknown and assumptions made for parameters such as: the amount of product applied; how often treatment is actually required; the number of applications that are typically

made; whether applications are generally spot or full lawn treatments, etc.

Similarly, a number of assumptions and best estimates are made in assessing post-application exposure, including: the duration and degree of activity in the treated area by children and adults; the amount of product available to dislodge and transfer to the skin during activity; and the amount of product dissipation over time.

Homeowner-use Products

End-use products containing the active ingredient, myclobutanil, are marketed for home use on roses, lawns, flowers, ornamental shrubs, and trees. The home use with the greatest potential for exposure is assumed to be lawn applications of the granular formulation with a handheld or push-type spreader or the application of a soluble concentrate to lawns with a hose-end, pump-up, or trigger bottle sprayer.

Handler Exposures and Assumptions

HED has determined that there is potential for intermittent short-term exposures to homeowners associated with typical end-product use of myclobutanil. Three exposure scenarios with the greatest potential for exposure are considered for application of myclobutanil to home lawns: 1)loading and application of granular product by hand held rotary granular spreader; 2)mixing, loading, and application of a soluble concentrate product by low pressure handwand sprayer; and 3)mixing, loading, and application of a soluble concentrate product by garden hose end sprayer.

Short-term dermal exposure assessments using the Pesticide Handlers Exposure Database (PHED) Version 1.1 surrogate data and risk calculations for homeowners are presented in Table 34. Table 35 summarizes data confidence and parameters specific to each exposure scenario and corresponding risk assessment.

TABLE 34. Short-Term and Intermediate-Term Exposure and Risk Assessments for Homeowner Use of Myclobutanil

Exposure Scenario	Dermal + Inhalation Unit Exposure (mg/lb ai)[a]	Maximum Application Rate (lb ai/acre)[b]	Maximum Acres/Day[c]	Total Daily Exposure (mg ai/day)[d]	Total Daily Dose (mg ai/kg/day)[e]		Short-Term MOE[f] (Using 60 kg BW)
					BW= 70 kg	BW= 60 kg	
1. Load/Apply Granular Using Belly Grinder Spreader	110.06	0.40	0.3	13.2	0.19	0.22	460
2. Load/Apply Soluble Concentrate Using Low Pressure Handwand	100.03	0.76	0.3	22.8	0.33	0.38	260
3. Load/Apply Soluble Concentrate Using Garden Hose End Sprayer	30.01	0.76	0.3	6.8	0.097	0.113	890

a Baseline unit exposure (dermal + inhalation), taken from PHED Version 1.1 data in the Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments dated December 18, 1997, represents short pants, short sleeve shirt, no gloves, and open loading. Note that for some PHED data correction factors were applied to arrive at the baseline scenario.

b Application rate comes from maximum rates found on the Myclobutanil labels for lawn treatment.

c Daily acres treated value is typical lawn size (Vinlove and Torla, 1995)

d Total Daily Exposure (mg ai/day) = Unit exposure (mg/lb ai) x Application Rate (lbs ai/acre) x Acres Treated.

e Total Daily Dose (mg/kg/day) = Daily Exposure (mg/day)/body weight (BW kg)

f Margin of Exposure (MOE) = NOEL (mg/kg/day)/Daily Dermal Dose (mg/kg/day)

Table 35. Exposure Scenario Descriptions for Selected Residential Uses of Myclobutanil

Exposure Scenario (Number)	Data Source	Typical Lawn Size [a]	Comments
Mixer/Loader/Applicator Descriptors			
Load/Apply GranularUsing Belly Grinder Spreader (1)	PHED V1.1	0.3 Acres	Medium confidence (20-45 replicates of ABC grade data) for dermal exposure. High confidence (40 replicates of AB grade data) for inhalation.
Load/Apply Soluble Concentrate Using Low Pressure Handwand (2)	PHED V1.1	0.3 Acres	Low confidence (9-80 replicates of ABC grade data) for dermal exposure. Medium confidence (80 replicates of ABC grade data) for inhalation.
Load/Apply Soluble Concentrate Using Garden Hose End Sprayer (3)	PHED V1.1	0.3 Acres	Low confidence (8 replicates of C and E grade data) for dermal exposure. Low confidence (8 replicates of C grade data) for inhalation. Based on one study.

[a] Based on Vinlove and Torla, 1995 (Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessment, December 18, 1997)

Homeowner Post-Application Exposures and Assumptions

The potential for post-application homeowner exposure exists. Potential exposures could be expected following applications to lawn and garden sites. There are no chemical-specific data to use in assessing these potential exposures. Post-application exposure is estimated and risk assessment performed using typical transfer coefficients (Tc) and surrogate dislodgeable foliar residues (DFR) derived from the application rate (Draft HED Standard Operating Procedures (SOPs) for Residential Exposure Assessment, December 18,1997). Short-term post-application exposure assessments and risk calculations for adults and toddlers reentering treated areas on the day of application are presented in Table 36.

Table 36. Post-application\ Exposure

DAT[a]	Surrogate DFR (μg/cm^2)[b]	Dose (mg/kg/day)[c]			Short-Term MOE[d]
		BW = 70 kg	BW = 60 kg	BW = 15kg	
Adults Dermal (Tc = 43,000 cm^2/hr)[e]					
0.00	0.85	0.24	0.28	NA	350 (Using 60 kg BW)
Toddlers Dermal (Tc = 8,700 cm^2/hr)[e]					
0.00	0.85	NA	NA	0.99	100
Toddlers Non-dietary Ingestion[f]					
0.00	0.85	NA	NA	0.06	1600
Toddlers Combined (Dermal +Non-dietary Ingestion)					
0.00	0.85	NA	NA	1.05	100

a DAT is days after treatment (0.00=day of application).
b Surrogate DFR (ug/cm^2) = Application Rate (0.76lb ai/A) x [(11.2 ug/cm^2)/(1 lb ai/A) conversion factor] x percent (10 percent assumed) of rate available as dislodgeable.
c Dermal Dose (mg/kg/day) = [DFR (ug/cm^2) x Tc (cm^2/hr) x (1 mg/1,000 μg unit conversion) x 2 hours/day] / Body Weight (BW kg).
d MOE = NOEL (mg/kg/day)/Dose (mg/kg/day).
e Transfer Coefficients from Draft HED Standard Operatiing Procedures (SOPs) for Residential Exposure Assessments, December 18, 1997.
f Oral Dose (mg/kg/day) = [DFR (ug/cm^2) x 3 yr old hand surface area (350cm^2) x 1 mg/1,000 (μg unit conversion) x Hand-to-Mouth Activity (1.56 events/hr) x 2 hours/day] / Body Weight (BW kg).

Using these exposure assumptions for short-term risk assessments, it is concluded that the MOEs that will result from the residential use of myclobutanil do not exceed HED's level of concern.

5. Food Quality Protection Act Considerations

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residues in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and

exposure through pesticide use in gardens, lawns, or buildings (residential and other outdoor and indoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

a. Potential Risks to Infants and Children

In assessing the potential for additional sensitivity of infants and children to residues of myclobutanil, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproductive toxicity study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during prenatal development. Reproduction studies provide information relating to pre- and post-natal effects from exposure to the pesticide, information on the reproductive capability of mating animals, and data on systemic toxicity.

b. Developmental and Reproductive Toxicity Studies.

i. Rats. In the developmental study (Accession #141672) in rats, the maternal (systemic) NOEL was 93.8 mg/kg/day, based on rough hair coat, and salivation at the LOEL of 312.6 mg/kg/day. The developmental (fetal) NOEL was 93.8 mg/kg/day based on incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day.

ii. Rabbits. In the developmental toxicity study (Accession #164971) in rabbits, the maternal (systemic) NOEL was 60 mg/kg/day, based on reduced weight gain, clinical signs of toxicity and abortions at the LOEL of 200 mg/kg/day. The developmental (fetal) NOEL was 60 mg/kg/day, based on increases in number of resorptions, decreases in litter size, and a decrease in the viability index at the LOEL of 200 mg/kg/day.

iii. Rats. In the 2-generation reproductive toxicity study (Accession #'s 143766 and 149581) in rats, the parental (systemic) NOEL was 2.5 mg/kg/day, based on increased liver weights and liver cell hypertrophy at the LOEL of 10 mg/kg/day. The developmental (pup) NOEL was 10 mg/kg/day, based on decreased pup body weight during lactation at the LOEL of 50 mg/kg/day. The reproductive NOEL was 10 mg/kg/day, based on the increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

c. Determination of Safety for Infants and Children

The pre- and post-natal toxicology data base for myclobutanil is complete with respect to current toxicological data requirements. Based on the developmental and reproductive toxicity studies discussed above, there does not appear to be an extra sensitivity for pre- or post-natal effects. Therefore, EPA concludes that reliable data support use of the 100-fold uncertainty factor and that an additional 10-fold factor is not needed to ensure the safety of infants and children from dietary exposure.

d. Aggregate Exposure and Risk for Infants and Children

i. Acute Aggregate Exposure and Risk for Infants and Children.

The acute dietary (food only) risk assessment is not required as the TESC did not identify any acute dietary risk endpoints.

ii. Chronic Aggregate Exposure and Risk for Infants and Children.

Using the partially refined exposure assumptions described above, HED has concluded that the percent of the RfD that will be utilized by dietary (food only) exposure to residues of myclobutanil ranges from 25% for nursing infants (<1 year old) up to 75% for non-nursing infants (<1 year old). The percent of the RfD that will be used by the food and water exposure for children (1-6 years old) is 62% (ie. 46% from food + 16% from water). Since there are no chronic residential uses of myclobutanil, a chronic aggregate risk assessment is not required.

e. Aggregate Exposure and Risk for U.S. population

i. Acute Aggregate Exposure and Risk.

This risk assessment is not required as the TESC did not identify any acute dietary risk endpoints.

ii. Chronic Aggregate Exposure and Risk.

Using the partially refined exposure assumptions described above, HED has concluded that aggregate exposure (food and water) to myclobutanil will not exceed HED's level of concern. The percent of the RfD that will be used by the food and water for children (1-6 years) is 62% (ie. 46% from food + 16% from water). For the U.S. population, the percent of RfD used by food and water is 21% [4.4% from water and 17% from food]. HED generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. HED has determined that the outdoor registered uses of myclobutanil would not fall under a chronic exposure scenario. HED concludes

that an aggregate chronic risk assessment is not required, since chronic residentional exposure is not present.

iii. Short- and Intermediate-Term Aggregate Exposure and Risk.

Since short-term residential exposure scenarios are present, RABI has determined the short term aggregate risks from turf use to 60 kg female adults and 15 kg toddlers [as shown below]. RABI concludes that short-term aggregate MOEs for adults and children are acceptable considering the default assumptions used in the derivation of exposure estimates and the fact that a LOEL was not identified in the 28-day rat dermal toxicity study [the HDT was the NOEL in this study] used to determine the MOE.

	Exposure to 60 kg Adult [mg/kg/day]	Exposure to 15 kg Toddler [mg/kg/day]
Food	0.004255	0.011492
Water	0.0013	0.004
Apply	0.28	
Reentry	0.38	1.05
Total	0.665555	1.065492

$$\text{Short-term Aggregate Adult MOE} = \frac{100 \text{ mg/kg/day}}{0.665555} = 150$$

$$\text{Short-term Aggregate Toddler MOE} = \frac{100 \text{ mg/kg/day}}{1.065492} = 94$$

f. Endocrine Disruptor Effects

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

Based on the adverse testicular findings in the chronic toxicity and reproduction studies in rats, myclobutanil should be considered as a candidate for evaluation as an endocrine disruptor.

g. Cumulative Risk from Exposure to Substances with a Common Mechanism of Toxicity

Myclobutanil is a member of the triazole class of systemic fungicides (The Pesticide Book, 4th ed., 1994). Other triazoles include bitertanol, cyproconazole, diclobutrazole, difenoconazole,

diniconazole, fenbuconazole, flusilazole, hexaconazole, penconazole, propiconazole, tebuconazole, tetraconazole, triadimefon, and triadimenol.

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether myclobutanil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of these tolerance actions, therefore, EPA has not assumed that myclobutanil has a common mechanism of toxicity with other substances.

Attachment 1: DRES Run: Chronic: W. Cutchin, 6/23/97

cc with Attachments 1 and 2: N. Dodd (RAB 1), B. Tarplee (RAB 1), M. Lamont (RAB 1), W. Dykstra (RAB 1), RAB 1 File, Caswell File, OREB File (#128857), PP#2E04141, SF
RDI: RAB1:12-FEB-1998

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.004139	0.005952	23.807128	7.251904	0.004255	17.01972
U.S. POPULATION - SPRING SEASON	0.003914	0.005624	22.494828	6.837964	0.004008	16.03145
U.S. POPULATION - SUMMER SEASON	0.004530	0.006333	25.331996	7.213420	0.004314	17.25707
U.S. POPULATION - FALL SEASON	0.004089	0.005955	23.818896	7.463276	0.004366	17.46522
U.S. POPULATION - WINTER SEASON	0.004001	0.005873	23.493788	7.490208	0.004308	17.23102
NORTHEAST REGION	0.004507	0.006339	25.355912	7.329784	0.004539	18.15719
NORTH CENTRAL REGION	0.004196	0.006004	24.017028	7.232888	0.004368	17.47235
SOUTHERN REGION	0.003340	0.004922	19.689516	6.330536	0.003577	14.30908
WESTERN REGION	0.004914	0.007106	28.423816	8.769604	0.004848	19.39143
HISPANICS	0.004795	0.007380	29.518340	10.336920	0.005049	20.19736
NON-HISPANIC WHITES	0.004215	0.006060	24.239212	7.379800	0.004324	17.29743
NON-HISPANIC BLACKS	0.003272	0.004477	17.907284	4.818884	0.003363	13.45043
NON-HISPANIC OTHERS	0.004299	0.006425	25.700248	8.502744	0.004425	17.70064
NURSING INFANTS (< 1 YEAR OLD)	0.009543	0.014037	56.147932	17.976872	0.006359	25.43698
NON-NURSING INFANTS (< 1 YEAR OLD)	0.024640	0.030308	121.233972	22.674608	0.018836	75.34262
FEMALES (13+ YEARS, PREGNANT)	0.002968	0.004246	16.985764	5.115344	0.003124	12.49575
FEMALES 13+ YEARS, NURSING	0.003798	0.005409	21.635288	6.442704	0.003932	15.72664
CHILDREN (1-6 YEARS OLD)	0.011418	0.016220	64.881224	19.210812	0.011492	45.96947
CHILDREN (7-12 YEARS OLD)	0.006439	0.009123	36.491708	10.736580	0.006910	27.63822
MALES (13-19 YEARS OLD)	0.003676	0.005310	21.239784	6.536892	0.004246	16.98476
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.003069	0.004419	17.674952	5.398156	0.003412	13.64812
MALES (20 YEARS AND OLDER)	0.002442	0.003683	14.732932	4.963320	0.002640	10.55916
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.002474	0.003682	14.726744	4.832204	0.002517	10.06981

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

ATTACHMENT I

TOLERANCE ASSESSMENT SUMMARY FOR Myclobutanil (Systane/Rally) DATE: 06/23/97
USING ANTICIPATED RESIDUES
CASWELL #723K

ANALYSIS FOR POPULATION SUB-GROUP: U.S. POPULATION - 48 STATES

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.003237	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	12.947	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000828	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	3.313	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.004065	MG/KG/DAY
THE NEW ARC WILL OCCUPY	16.261	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000190	MG/KG/DAY
THIS ARC WILL OCCUPY	0.759	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.004255	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	17.020	% OF THE ADI.

ANALYSIS FOR POPULATION SUB-GROUP: NON-NURSING INFANTS (< 1 YEAR OLD)

EXISTING ANTICIPATED RESIDUES (PUBLISHED ONLY)		
RESULT IN AN ARC OF:	0.017361	MG/KG/DAY
THE EXISTING ARC IS EQUIVALENT TO:	69.444	% OF THE ADI.
PROPOSED NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
RESULT IN AN ARC OF:	0.000545	MG/KG/DAY
THESE NEW ANTICIPATED RESIDUES WILL OCCUPY:	2.178	% OF THE ADI.
IF THE NEW ANTICIPATED RESIDUES (CURRENT PETITION ONLY)		
ARE APPROVED THE RESULTANT ARC WILL BE:	0.017906	MG/KG/DAY
THE NEW ARC WILL OCCUPY	71.622	% OF THE ADI.
OTHER PENDING ANTICIPATED RESIDUES EXCLUDING THE		
CURRENT NEW PETITION HAVE AN ARC OF:	0.000930	MG/KG/DAY
THIS ARC WILL OCCUPY	3.721	% OF THE ADI.
IF ALL PENDING ANTICIPATED RESIDUES (INCLUDING THE		
CURRENT NEW PETITION) ARE GRANTED		
THE RESULTANT ARC WILL BE:	0.018836	MG/KG/DAY
THE TOTAL ARC WILL OCCUPY	75.343	% OF THE ADI.

ANTICIPATED RESIDUE INFORMATION FOR CASWELL NUMBER 723K DATE: 06/23/97 PAGE: 1

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
01014AA	GRAPES-FRESH	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014AA	GRAPES-FRESH	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014AA	GRAPES-FRESH	31 COOKED-FRESH OR CANNED	7F3476	P 1.000000	1.000000		79.00	0.790000
01014DA	GRAPES-RAISINS	10 RAW-FRESH OR NFS	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014DA	GRAPES-RAISINS	21 COOKED-NFS	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014DA	GRAPES-RAISINS	22 COOKED-FRESH-BAKED	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014JA	GRAPES-JUICE	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014JA	GRAPES-JUICE	15 RAW-FRESH OR CANNED	7F3476	P 1.000000	1.000000		79.00	0.790000
01014JA	GRAPES-JUICE	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01016AA	STRAWBERRIES	10 RAW-FRESH OR NFS	97FL001	P 0.500000	0.500000		100.00	0.500000
01016AA	STRAWBERRIES	21 COOKED-NFS	97FL001	P 0.500000	0.500000		100.00	0.500000
01016AA	STRAWBERRIES	70 RAW-FROZEN	97FL001	P 0.500000	0.500000		100.00	0.500000
03001AA	ALMONDS	10 RAW-FRESH OR NFS	0F3876	P 0.100000	0.100000		1.00	0.001000
03001AA	ALMONDS	21 COOKED-NFS	0F3876	P 0.100000	0.100000		1.00	0.001000
03001AA	ALMONDS	22 COOKED-FRESH-BAKED	0F3876	P 0.100000	0.100000		1.00	0.001000
04001AA	APPLES-FRESH	10 RAW-FRESH OR NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	21 COOKED-NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	31 COOKED-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	10 RAW-FRESH OR NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	22 COOKED-FRESH-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001JA	APPLES-JUICE	15 RAW-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001JA	APPLES-JUICE	31 COOKED-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04002AA	CRABAPPLES	00 NOT SPECIFIED (NO CONSUMPTION)	9F3812	A 0.500000	0.500000		100.00	0.500000
04003AA	PEARS-FRESH	10 RAW-FRESH OR NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	31 COOKED-FRESH OR CANNED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	51 COOKED-CANNED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003DA	PEARS-DRIED	10 RAW-FRESH OR NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04003DA	PEARS-DRIED	21 COOKED-NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04004AA	QUINCES	00 NOT SPECIFIED (NO CONSUMPTION)	9F3812	A 0.500000	0.500000		100.00	0.500000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001AA	APRICOTS-FRESH	21 COOKED-NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001AA	APRICOTS-FRESH	31 COOKED-FRESH OR CANNED	1F3954	P 2.000000	2.000000		1.00	0.020000
05001DA	APRICOTS-DRIED	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001DA	APRICOTS-DRIED	22 COOKED-FRESH-BAKED	1F3954	P 2.000000	2.000000		1.00	0.020000
05002AA	CHERRIES-FRESH	10 RAW-FRESH OR NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	21 COOKED-NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	31 COOKED-FRESH OR CANNED	2F4116	P 5.000000	5.000000		47.00	2.350000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
05002AA	CHERRIES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	2F4116	P 5.000000	5.000000		47.00	2.350000
05002DA	CHERRIES-DRIED	00 NOT SPECIFIED (NO CONSUMPTION)	2F4116	P 5.000000	5.000000		47.00	2.350000
05002JA	CHERRIES-JUICE	15 RAW-FRESH OR CANNED	2F4116	P 5.000000	5.000000		47.00	2.350000
05002JA	CHERRIES-JUICE	21 COOKED-NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05003AA	NECTARINES	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		21.00	0.420000
05004AA	PEACHES-FRESH	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	21 COOKED-NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	31 COOKED-FRESH OR CANNED	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	51 COOKED-CANNED	9F3811	P 2.000000	2.000000		22.00	0.440000
05004DA	PEACHES-DRIED	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004DA	PEACHES-DRIED	21 COOKED-NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05005AA	PLUMS-FRESH	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		3.00	0.060000
05005AA	PLUMS-FRESH	31 COOKED-FRESH OR CANNED	1F3954	P 2.000000	2.000000		3.00	0.060000
05005DA	PLUMS-PRUNES	10 RAW-FRESH OR NFS	1H5608	P 8.000000	8.000000C		3.00	0.240000
05005DA	PLUMS-PRUNES	21 COOKED-NFS	1H5608	P 8.000000	8.000000C		3.00	0.240000
05005DA	PLUMS-PRUNES	31 COOKED-FRESH OR CANNED	1H5608	P 8.000000	8.000000C		3.00	0.240000
05005JA	PRUNE-JUICE	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		3.00	0.060000
05005JA	PRUNE-JUICE	62 COOKED-FRESH OR FROZEN-BAKED	1F3954	P 2.000000	2.000000		3.00	0.060000
06002AA	BANANAS-UNSPEC	22 COOKED-FRESH-BAKED	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	10 RAW-FRESH OR NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	31 COOKED-FRESH OR CANNED	2E04141	A 4.000000	0.800000		100.00	0.800000
06002DA	BANANAS-DRIED	10 RAW-FRESH OR NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002DA	BANANAS-DRIED	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	23 COOKED-FRESH-BOILED	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	25 COOKED-FRESH-FRIED	2E04141	A 4.000000	0.800000		100.00	0.800000
10002AA	CANTALOUPES-UNSP	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10002AB	CANTALOUPES-PULP	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10002AB	CANTALOUPES-PULP	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10003AA	CASABAS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10004AA	CRENSHAWS	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10005AA	HONEYDEW MELONS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10007AA	PERSION MELONS	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10008AA	WATERMELON	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10008AA	WATERMELON	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	11 RAW-FRESH-PICKLED,CORNED,OR CURED	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000

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Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#		TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
10011AA	PUMPKIN	22 COOKED-FRESH-BAKED	SECT18	P	0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	62 COOKED-FRESH OR FROZEN-BAKED	SECT18	P	0.300000	0.300000		100.00	0.300000
10013AA	SQUASH-SUMMER	10 RAW-FRESH OR NFS	SECT18	P	0.300000	0.300000		100.00	0.300000
10013AA	SQUASH-SUMMER	21 COOKED-NFS	SECT18	P	0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	10 RAW-FRESH OR NFS	SECT18	P	0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	21 COOKED-NFS	SECT18	P	0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	31 COOKED-FRESH OR CANNED	SECT18	P	0.300000	0.300000		100.00	0.300000
10017AA	BITTER MELON	21 COOKED-NFS	SECT18	P	0.300000	0.300000		100.00	0.300000
10020AA	TOWELGOURD	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P	0.300000	0.300000		100.00	0.300000
11003AA	PEPPERS,SWEET	10 RAW-FRESH OR NFS	97CA036	P	1.000000	1.000000		100.00	1.000000
11003AA	PEPPERS,SWEET	21 COOKED-NFS	97CA036	P	1.000000	1.000000		100.00	1.000000
11003AB	CHILI PEPPERS	00 NOT SPECIFIED (NO CONSUMPTION)	97CA036	P	1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	10 RAW-FRESH OR NFS	97CA036	P	1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	21 COOKED-NFS	97CA036	P	1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	51 COOKED-CANNED	97CA036	P	1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	10 RAW-FRESH OR NFS	97CA036	P	1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	21 COOKED-NFS	97CA036	P	1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	31 COOKED-FRESH OR CANNED	97CA036	P	1.000000	1.000000		100.00	1.000000
11005AA	TOMATOES-WHOLE	10 RAW-FRESH OR NFS	97CA042	N	0.300000	0.300000		100.00	0.300000
11005AA	TOMATOES-WHOLE	21 COOKED-NFS	97CA042	N	0.300000	0.300000		100.00	0.300000
11005AA	TOMATOES-WHOLE	31 COOKED-FRESH OR CANNED	97CA042	N	0.300000	0.300000		100.00	0.300000
11005JA	TOMATOES-JUICE	10 RAW-FRESH OR NFS	97CA042	N	0.300000	0.300000		100.00	0.300000
11005JA	TOMATOES-JUICE	21 COOKED-NFS	97CA042	N	0.300000	0.300000		100.00	0.300000
11005RA	TOMATOES-PUREE	10 RAW-FRESH OR NFS	97CA042	N	0.600000	0.600000		100.00	0.600000
11005RA	TOMATOES-PUREE	21 COOKED-NFS	97CA042	N	0.600000	0.600000		100.00	0.600000
11005RA	TOMATOES-PUREE	31 COOKED-FRESH OR CANNED	97CA042	N	0.600000	0.600000		100.00	0.600000
11005RA	TOMATOES-PUREE	32 COOKED-FRESH OR CANNED-BAKED	97CA042	N	0.600000	0.600000		100.00	0.600000
11005RA	TOMATOES-PUREE	51 COOKED-CANNED	97CA042	N	0.600000	0.600000		100.00	0.600000
11005TA	TOMATOES-PASTE	21 COOKED-NFS	97CA042	N	1.200000	1.200000		100.00	1.200000
11005TA	TOMATOES-PASTE	22 COOKED-FRESH-BAKED	97CA042	N	1.200000	1.200000		100.00	1.200000
11005TA	TOMATOES-PASTE	31 COOKED-FRESH OR CANNED	97CA042	N	1.200000	1.200000		100.00	1.200000
11005UA	TOMATOES-CATSUP	21 COOKED-NFS	97CA042	N	0.600000	0.600000		100.00	0.600000
16002AA	ASPARAGUS	21 COOKED-NFS	97CA026	P	0.010000	0.010000		100.00	0.010000
16002AA	ASPARAGUS	23 COOKED-FRESH-BOILED	97CA026	P	0.010000	0.010000		100.00	0.010000
27003OA	COTTONSEED-OIL	18 PROCESSED OIL	4F4317	P	0.020000	0.020000		1.00	0.000200
27003MA	COTTONSEED-MEAL	18 PROCESSED OIL	4F4317	P	0.020000	0.020000		1.00	0.000200
28080AA	PEPPERMINT	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	P	2.500000	2.500000		100.00	2.500000
28080OA	PEPPERMINT-OIL	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	P	2.500000	2.500000		100.00	2.500000
28081AA	SPEARMINT	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	P	2.500000	2.500000		100.00	2.500000
28081OA	SPEARMINT-OIL	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	P	2.500000	2.500000		100.00	2.500000

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Nyclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

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43058AA	WINE AND SHERRY	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
43058AA	WINE AND SHERRY	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
50000DB	MILK-NON-FAT SOL	10 RAW-FRESH OR NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000DB	MILK-NON-FAT SOL	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000DB	MILK-NON-FAT SOL	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	10 RAW-FRESH OR NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
50000SA	MILK SUG (LACT)	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000SA	MILK SUG (LACT)	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BA	BEEF-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BA	BEEF-MEAT BYP	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BB	BEEF-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BB	BEEF-OTH ORGAN	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001DA	BEEF-DRIED	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001FA	BEEF-FAT	10 RAW-FRESH OR NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	22 COOKED-FRESH-BAKED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	24 COOKED-FRESH-BROILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001KA	BEEF-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001LA	BEEF-LIVER	25 COOKED-FRESH-FRIED	0F3876	P 1.000000	1.000000		100.00	1.000000
53001LA	BEEF-LIVER	31 COOKED-FRESH OR CANNED	0F3876	P 1.000000	1.000000		100.00	1.000000
53001MA	BEEF-LEAN	10 RAW-FRESH OR NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53002BA	GOAT-MEAT BYP	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002BB	GOAT-OTH ORGAN	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002FA	GOAT-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53002FA	GOAT-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53002KA	GOAT-KIDNEY	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002LA	GOAT-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53002MA	GOAT-LEAN	23 COOKED-FRESH-BOILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53002MA	GOAT-LEAN	25 COOKED-FRESH-FRIED	0F3876	P 0.100000	0.100000		100.00	0.100000
53003AA	HORSE	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53005BA	SHEEP-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005BB	SHEEP-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000

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53005FA	SHEEP-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53005KA	SHEEP-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005LA	SHEEP-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53005MA	SHEEP-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53005MA	SHEEP-LEAN	31 COOKED-FRESH OR CANNED	0F3876	P 0.100000	0.100000		100.00	0.100000
53006BA	PORK-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006BB	PORK-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006BB	PORK-OTH ORGAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.200000	0.200000		100.00	0.200000
53006FA	PORK-FAT	10 RAW-FRESH OR NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006KA	PORK-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006LA	PORK-LIVER	21 COOKED-NFS	0F3876	P 1.000000	1.000000		100.00	1.000000
53006LA	PORK-LIVER	25 COOKED-FRESH-FRIED	0F3876	P 1.000000	1.000000		100.00	1.000000
53006MA	PORK-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53006MA	PORK-LEAN	25 COOKED-FRESH-FRIED	0F3876	P 0.100000	0.100000		100.00	0.100000
53006MA	PORK-LEAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.100000	0.100000		100.00	0.100000
55008BA	TURKEY-BYP	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008BA	TURKEY-BYP	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008LA	TURKEY ORGAN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008LA	TURKEY ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MB	TURKEY+SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MB	TURKEY+SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MC	TURKEY-UNSPEC	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55013BA	POULTRY,OTH-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	7F3476	P 0.020000	0.020000		100.00	0.020000
55013LA	POULTRY,ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55013MA	POULTRY,OTHER	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	23 COOKED-FRESH-BOILED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000

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Chemical:	**Myclobutanil**
PC Code:	**128857**
HED File Code	**13000 Tox Reviews**
Memo Date:	**02/12/98**
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